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UNOFFICIAL TRANSCRIPT*
WASHINGTON STATE
PHARMACY AND THERAPEUTICS COMMITTEE MEETING
February 17, 2010
Sea Tac Marriott Hotel
9:00am – 4:00pm

Vyn Reese: I'd like to welcome everyone to the Washington State Pharmacy and Therapeutics Committee Meeting and we'll start today with introductions. We'll begin on my left. Go ahead.

Chuck Agte: Chuck Agte with Health and Recovery Services Administration.

Siri Childs: Siri Childs, Pharmacy Administrator with Washington Medicaid.

Jaymie Mai: Jaymie Mai with Labor and Industries.

Doug Tuman: Doug Tuman with Labor and Industries.

Jeff Graham: This is Jeff Graham from the Health Care Authority. I'm going to break from it a little bit here. I'd like to introduce our three new members before we come to them. We have Christine Klingel. Christine is a pharmacist from Wenatchee and I believe you're with one of the community clinic…

Christine Klingel: Columbia Valley Community Health.

Jeff Graham: Susan Rowe. Susan is a pharmacist from the Tacoma area with the Tacoma Family…Multi-Care Healthcare and Tacoma Family Medicine and Debra Wiser who's from Spokane. Nice familiar face. I didn't really know Debra but she's at the same clinic I was in when I left Spokane. So it's nice to have a family physician from Spokane.

* For copies of the official audio taped record of this meeting, please contact Regina Chacon at (206)521-2027 pdp@hca.wa.gov.

Ken Wiscomb: Ken Wiscomb, P&T Committee.

Patti Varley: Patti Varley, P&T Committee.

Deb Wiser: Deb Wiser, family doctor from Spokane.

Vyn Reese: Vyn Reese, Chair.

Carol Cordy: Carol Cordy, P&T Committee.

Susan Rowe: Susan Rowe, P&T Committee.

Jason Iltz: Jason Iltz, pharmacist and P&T Committee Member.

Regina Chacon: Regina Chacon, Health Care Authority.

Leta Evaskus: Leta Evaskus, Health Care Authority.

Donna Sullivan: Donna Sullivan with the Health Care Authority.

Duane Thurman: Duane Thurman with the Health Care Authority and I'd just like to remind everyone to speak into the microphones. We're transcribing the meeting. Thank you.

Ray Hanley: Ray Hanley, Health Care Authority.

Andre Rossi: Andre Rossi, Department of Corrections.

Vyn Reese: Okay. Now Jeff, do you have any additional announcements?

Jeff Graham: Yes. We have a couple of clarifications that we have to do and I think…Gerald, are you on the phone? I heard somebody come in. Well, I hope he's on the phone there maybe listening. But we have these two clarifications to do from a previous meeting. There were a couple of questions afterwards.

We have the TZDs here that we did make a motion and pass at the present meeting, but we were actually…when we did that we were referring to the wrong motion and so we want to make certain that we wanted to…I think it's the December 17, 2008 motion that we thought we were passing, but

we put up the wrong one. We put up the one from February of 2008. So you can see on this paper what we…what we think you actually meant to do. So if you could read through that.

Vyn Reese: Okay. So as I understand it, Jeff, the wrong template was up and we…

Jeff Graham: The wrong template was up.

Vyn Reese: …came to that part of the agenda and we passed the motion from the meeting before instead of the last meeting.

Jeff Graham: Yes. Right. Yes.

Vyn Reese: So I'd like to have you refer to the…the committee refer to the P&T motion history on TZDs and so what we should be actually passing would be the December 17, 2008 motion, which by error we passed the one from the meeting before. So I'll take that motion. The one that is underlined under TZDs. Can I get a volunteer to make that motion?

Ken Wiscomb: This is Ken Wiscomb. I'll reiterate the motion from December 17, 2008.

Carol Cordy: I'll second it.

Vyn Reese: All those in favor say, "Aye".

Group: Aye.

Vyn Reese: Opposed, same sign. The motion's passed. We had a problem with the MS drug motion too. Is that right?

Jeff Graham: Well, there was a new product out that had a…its own brand name, Extavia, which is actually the same chemical as the betaseron. So we were…we wanted guidance on that. Do we want both of those covered or is it okay that we could…if there was a difference the pricing for the agencies. Do we have to have both of them on or could we have just one on?

Vyn Reese: So the way I understand it is it says [inaudible] beta 1B SQS2 brands available betaseron and Extavia. Both betaseron and Extavia have the

same active ingredient and we just need to add…either a drug would be acceptable for the PDL. Is that right?

Jeff Graham: If that's what you'd like to do, yes.

Vyn Reese: Is there any discussion about that in the committee?

Patti Varley: This is Patti Varley. Just for clarification, um, there was no data presented showing any difference between those two brand names. They are just different brands of the same agent. Correct?

Vyn Reese: Yes.

Jason Iltz: This is Jason. I don't remember us ever making a motion where we…if we recommend that the medication's covered or on the Preferred List that we refer to them as branded. They are brand names. So my understanding would be that, you know, as long as there's a representative agent from each of the generics that are listed there, the generic names, that that would suffice for the motion as I understand we meant it to be. Is that correct?

Vyn Reese: Exactly. So you could just say one interferon beta 1B needs to be on the Preferred Drug List if you wanted to add that as the next sentence. In fact, you can make that motion if you'd like.

Patti Varley: This is Patti Varley. That confuses me a bit because if you look at the motion it has the generic name of the two brands listed already within the motion. Um, so do we need to do anything?

Vyn Reese: What it does is it frees up the bids strategy to…depending on which one of those drugs is the least expensive as I understand it.

Patti Varley: Again, Patti Varley. This is what it says in the motion is the generic name. There are two brands. Isn't that common that there's more than one brand of a drug and therefore why is this…I'm just curious. I'm confused as to why is this different?

Jeff Graham: I think Donna has a comment.

Donna Sullivan: I'm sorry. What were you…repeat the question.

Patti Varley: Okay. So this is Patti Varley again. If you look within the motion it says after considering the evidence, safety, efficacy of special populations for MS it lists interferon beta 1ASQ there. Even though that comes in two brands we don't usually comment about which brand. We just usually say that that agent…

Duane Thurman: I guess we're just trying to be very careful about how we do this, you know, the last statement is all medications should be preferred on the Washington Preferred Drug List and so…

Patti Varley: But as long as one of them is, the interferon B…

Duane Thurman: And that's just what we want to clarify.

Patti Varley: Yeah. We've never cared about what brand you pick in that. We just want to make sure that that agent is available.

Duane Thurman: We are being overly cautious.

Carol Cordy: This is Carol Cordy. So do we need to put, you know, propose a whole new motion?

Duane Thurman: Well, I think you could just take a vote that you want to clarify that of the medications…well, it would be best if you said between the two beta interferons that we have to have had at least one.

Jason Iltz: This is Jason. If we were to just modify the last sentence there of the motion to say, um, a representative agent from each of the disease modifying medications should be preferred on the Washington Preferred Drug List. Would that clarify it?

Duane Thurman: Exactly.

Patti Varley: Okay. This is Patti Varley and I feel much more comfortable with that because I'm concerned that we could get ourselves into deep trouble if we were always referring to specific brand names for particular agents. We'd have to redo every motion we've ever made.

Duane Thurman: You're absolutely right.

Patti Varley: Thank you.

Jason Iltz: So let me make that official then as a motion or as an amended motion that we modify our December 16, 2009 motion. The last sentence to read a representative agent from each of the disease modifying medications should be preferred on the Washington Preferred Drug List.

Patti Varley: I would second that amendment. That's Patti Varley.

Jeff Graham: Gerald is that you?

Gerald Gartlehner: Hello?

Jeff Graham: Yeah, okay. We've got you in now. Thanks.

Vyn Reese: We should say a representative agent from each of these…drug class…

Jason Iltz: Each of the disease modifying medications.

Vyn Reese: Right. Drug classes needs to be on.

Jason Iltz: Disease modifying classes. Yes.

Woman: Do we need preferred twice?

Carol Cordy: If it's going to be a preferred.

Jason Iltz: From each of the disease modifying medication classes should be preferred on the Preferred Drug List.

Vyn Reese: You can just say should be on the Preferred Drug List instead of should be preferred on the Preferred Drug List.

Carol Cordy: No. It has to be preferred.

Siri Childs: Yes.

Vyn Reese: Is that your motion?

Jason Iltz: Yes. That's correct as stated.

Vyn Reese: Any discussion? Take a second.

Man: Patti already seconded.

Patti Varley: Patti Varley, I'll second again.

Vyn Reese: All those in favor say, "Aye".

Group: Aye.

Vyn Reese: Opposed, same sign. The motion's passed.

Jason Iltz: This is Jason. I wanted to clarify one other thing to you because after the meeting last time I may have incorrectly assumed something and one of these medications on this list is subject to a very strict monitoring program and safety program called TOUCH which makes it available for certain patients under certain conditions which also means that they have to meet very specific criteria for its use. And so that medication is Tysabri and I had noticed on the Preferred Drug List that there was a prior authorization process that was in place and I assumed that would stay in place. But we didn't actually say that. My assumption was that since it's an FDA mandated process that it has to stay in place. But is that true or do we need to make a statement as a P&T Committee that we support it still going through a prior authorization process to meet all the criteria that are set forth by the FDA?

Siri Childs: This is Siri Childs speaking for Medicaid and yes, you know, Medicaid always appreciates the support statements from the P&T Committee. But we will have it on PAA regardless. So one way or another we appreciate a support statement.

Duane Thurman: This is Duane. I think that your support statement will be in the transcript. I think the PA will follow the FDA guidelines and continue.

Jason Iltz: Okay. Thank you.

Vyn Reese: Okay. I think that's the end of the old business section of the meeting. So are we ready to go with the update? We'll now begin the update on the targeted immune modulators. Are you ready online there?

Jeff Graham: Gerald, are you still there?

Gerald Gartlehner: I'm still here. Yes.

Jeff Graham: Okay. Your slides are coming up so we'll be ready to go.

Gerald Gartlehner: Okay. Well, thank you. So today's presentation is on the second update of our review on targeted immune modulators and because we have added new indications and also because we have really revamped this report the presentation will be a bit longer than the usual update. So please bear with me.

Let's get started on slide 2. Slide 2 summarizes the included medications. We have added two new medications for this update – Certolizumab and Natalizumab. Certolizumab is a [inaudible] of [inaudible] inhibitor. It's administered subcutaneously every two to four weeks and currently it is FDA approved for the treatment of rheumatoid arthritis and Crohn's disease. Another [inaudible] of the second one is an IGG4 inhibitor. The administration is intravenously every 30 to 60 days and Natalizumab has been approved for [inaudible].

We have also dropped one drug – Raptiva Efalizumab. Raptiva has been taken off the market because of an increased risk of progressive multifocal leukoencephalopathy which is a severe rapidly progressive viral infection of the central nervous system that can lead to death and adult [inaudible] visibility. Slide 3.

Slide 3 summarizes our indications of interest. As I've said we've added new indications, new pediatric indications for this update, which are psoriatic arthritis, Crohn's disease, ulcerative colitis and plaque psoriasis. No changes have been made for adult indications. Slide 4.

Our outcomes of interest are listed among slide 4 and 5 and they're basically still the same. We still focus on health outcomes but because of its clinical importance we have now added radiographic progression as an intermediate outcome. And then slide 6.

Slide 6 shows our included study designs and just to remind you one of the unique aspects of this report is that we are also including observational studies…prospective observational studies for effectiveness. So most of the other reports are focused on RCTs for effectiveness. Slide 7.

Overall our report now includes 236 studies. So it's a very large report and it is a drug class where there's a lot of research going on and all of these drugs are constantly undergoing new research and new studies. Slide 8.

So [inaudible] for rheumatoid arthritis for the comparative effectiveness of this drugs for rheumatoid arthritis we have included seven head-to-head studies. Two of those were RCTs and just to remind you this is a drug class where we had very little head-to-head evidence in the last two reports and where we have relied on indirect comparisons to draw some conclusions in the earlier reports. Slide 9.

So what this new evidence shows us based on what randomized controlled trial we found similar effectiveness between abatacept and infliximab after six months of treatment and we also found similar effectiveness between adalimumab and etanercept. The evidence for this comparison, however, needs to be viewed a bit with caution because it is limited to one prospective cohort study and four indirect comparisons of placebo-controlled trials. Slide 10.

The evidence is mixed on the comparison of adalimumab and infliximab. A prospective cohort study reported better response rates after one year for adalimumab and infliximab. This study however was rather small and these findings are not supported by the indirect comparisons of RCTs but then these RCTs are all shorter than one year. They are usually three to six months. Our conclusion has not changed regarding the comparative effectiveness of anakinra with NTTs drugs. We are still saying that NTTs drugs are more effective than anakinra and in the meantime this has also been concerned by other studies employing indirect comparisons. Slide 11.

We have evidence of moderate strength now that etanercept is more effective than infliximab and this conclusion is based on one open label RCT, one non-randomized trial and four prospective cohort studies and of

course all of these studies by themselves have methodological shortcomings. But the consistency of the findings is striking. All of these studies showed better response rates for etanercept and infliximab after one year of treatment. And a couple of slides before I said that abatacept and infliximab are equally efficacious and this was a six-month…there was an extension study up to one year where abatacept and [inaudible] fared better than infliximab. So it seems like infliximab is losing its efficacy over time a bit. And for rheumatoid arthritis we still do not have any evidence on all of the other comparisons, particularly the newer drugs.

Slide 12 there are multiple systematic reviews and RCTs that confirm the general efficacy of all of these drugs. We have summarized these studies in the report so if you're interested in more details it's all in the report. Slide 13.

Juvenile idiopathic arthritis we still do not have any head-to-head evidence for juvenile idiopathic arthritis for RCTs confirmed the general efficacy of abatacept, adalimumab, etanercept and infliximab. Slide 14.

Most of these studies, three out of four of these studies have some methodological issues that compromise the external validity of these studies. The three studies have active running periods and during these running periods they have excluded outpatients who either did not respond, had intolerable adverse effects, or lacked adherence and after the active running period then the randomization phase started. Slide 15.

The general efficacy of these drugs for the treatment of juvenile idiopathic arthritis however is well established and as you can see on this slide treatment effects are large compared to placebo. Slide 16.

Ankylosing spondylitis – for ankylosing spondylitis we still do not have any direct head-to-head evidence. We have included one meta-analysis with indirect comparisons and this study showed no differences in effectiveness between adalimumab, etanercept and infliximab.

Slide 17 we have nine RCTs and one systematic review that confirms the general efficacy of these drugs for the treatment of ankylosing spondylitis and as you can see them on slide 18 the treatment effects are also large compared to placebo. The 20% response rate for targeted immune

modulators for example were 57 to 80% compared with 20 to 30% for placebo. Slide 19.

Psoriatic arthritis – for psoriatic arthritis it's pretty much the same situation. We still do not have any head-to-head evidence. We have included one meta-analysis with indirect comparisons which also showed no differences in effectiveness between adalimumab, etanercept and infliximab. But then again it's an indirect comparison and it always had some methodological [inaudible] if you do those. Slide 20.

This was one of the new indications – psoriatic arthritis for children. We did not find any evidence for or against the effectiveness of targeted immune modulators for the treatment of psoriatic arthritis in children. For adults we have six RCTs and one meta-analysis that confirmed the general efficacy of adalimumab, alefacept, etanercept and infliximab for the treatment of psoriatic arthritis. Slide 21.

Again, treatment effects compared with placebo are large – 40 to 50% respond compared with 0 to 10% on placebo. Slide 22.

Crohn's disease – again we do not have any direct or indirect head-to-head evidence for the treatment of Crohn's disease. The best available evidence for a pediatric population was one [inaudible] ranging study without a placebo-controlled arm and in this study about 88% of children responded to treatment after 10 weeks. Slide 23.

In adults the evidence base is fairly solid regarding the general efficacy of adalimumab, Certolizumab, infliximab and natalizumab.

Then on slide 24 again you can see the effect sizes up to 57% patients treated with infliximab [inaudible] achieved remission compared with up to 30% of patients on placebo. Slide 25.

The whole situation is a bit different for ulcerated colitis. Again we do not have any head-to-head evidence, but the evidence on the general efficacy is also not very good. The only two RCTs that are available on infliximab and both of them were rated as poor because of very high dropout rates. Without really telling you the publication, the reasons for the dropout. Slide 26.

Plaque psoriasis – once again we did not find any comparative effectiveness. The only evidence available on children is one RCT that showed the general efficacy of etanercept for the treatment of plaque psoriasis in children.

The on slide 27 once again the evidence base is much better for the treatment of plaque psoriasis in adults. 11 RCTs and 2 MAs analysis showed the general efficacy of adalimumab, alefacept, etanercept and infliximab.

And as you can see on slide 28 these drugs really work very well for plaque psoriasis 60 to 80% response rates on the PASI 75, which is a 75% improvement of symptoms compared with 5 to 20% for [inaudible] treated with placebo. Slide 29.

Adverse events – from the head-to-head studies that we now have for rheumatoid arthritis we can make some inferences regarding the comparative risk of harms and the double-blinded RCT that I've mentioned in the beginning…reported that infliximab actually has higher rates of serious adverse events, some serious infections than abatacept. The rates actually were substantially higher. So 18% with infliximab. It was at 18% of patients with serious adverse events with infliximab compared with 9.6% with abatacept and 8.5% of patients on the infliximab had serious infections compared with 1.9% on abatacept. No differences in adverse events was found between etanercept and infliximab. Slide 30.

The evidence is strong that a combination of two targeted immune modulators really increases the risks of adverse events without adding any additional benefit. This is based on two RCTs and this is also the conclusion for adverse events that we have rated with high strength of evidence. Slide 31.

Of course there are well known risks of serious adverse events for targeted immune modulators such as malignancies, congestive heart failure, hepatotoxicity and others. For most of these we do not have enough evidence to draw conclusions about the comparative risks among targeted immune modulators. Slide 32.

For some adverse events, however we have some evidence on the comparative risk of harms. For example injection site reaction. Injection

site reaction clearly occur more commonly in Anakinra than any other subcutaneous targeted immune modulators and infusion reactions appear to occur more commonly with rituximab than with other targeted immune modulators particularly during the first infusion of rituximab. Slide 33.

Long-term evidence is still lacking for so many of these drugs, particularly for the newer ones and there is also hardly any evidence on the safety of targeted immune modulators in children. Slide 34.

Subgroups unfortunately there is also the lack of evidence on subgroups. At the moment the evidence is insufficient to draw any conclusions about the comparative effectiveness and safety in subgroups. Slide 35.

As we were writing this report a new targeted immune modulator was approved by the FDA for the treatment of rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis. It is golimumab Simponi. It's a self-injectable NTF drug and as far as we could tell from the quick literature [inaudible] more head-to-head evidence is available yet and we will include golimumab for the next update. This is my last slide. Thank you for your attention and if you have any questions I'd be happy to answer them.

Vyn Reese: Thank you. This is Dr. Reese. Are there any questions from the committee? Gerald, I'd like you to stay on the line while there is stakeholder comment and you can just comment on their comments if needed. I'd like to open the meeting now to stakeholder comments. I want to remind the stakeholders that they have three minutes to talk and you'll be timed. A hook will come out and grab you if you speak too long. All right? The first person up is Mr. Marc Jensen from UCB Pharma. On deck is Dr. Jeff Peterson of Washington Rheumatology Alliance.

Marc Jensen: Thank you and good morning committee members. My name is Mark Jensen and I'm a Medical Science Liaison for UCB Pharma. And again thank you for the opportunity to present Cimzia or certolizumab pegol data following the recent rheumatoid arthritis approval or indication. Certolizumab pegol is a unique anti TNF biologic. It's the only pegylated anti TNF agent and pegylation prolongs the circulation time of the protein and allows for reduced dosing frequency. Cimzia was initially approved in April of 2008 for the treatment of Crohn's disease specifically to reduce signs and symptoms and to maintain clinical response in adults with

moderate to severely active Crohn's disease who have not responded to conventional therapy.

In May of 2009 Cimzia was approved for the treatment of adults with moderately to severely active rheumatoid arthritis. For the treatment of rheumatoid arthritis Cimzia is dosed with an initial loading dose of 400 mg at week 0, 2 and 4 followed by 200 mg every two weeks or 400 mg once a month. It can be used in combination with methotrexate or as monotherapy and it offers long-term stable dosing as demonstrated by their factors. There's no difference in response observed when Cimzia was administered as 400 mg a month in our clinical trials versus 800 mg a month in the two pivotal phase 3 trials.

Additionally, in the long-term open label extension rheumatoid arthritis trial increasing the maintenance dose from 400 mg a month to 800 mg a month did not appear to result in additional efficacy. Cimzia's available in the original [inaudible] formulation as well in a 200 mg per ML pre-filled syringe.

In three pivotal phase 3 trials in patients with RA Cimzia-treated patients experienced significant relief in signs and symptoms of rheumatoid arthritis based on the ACR 20, 50 and 70 response criteria whether administered as monotherapy or in combination with methotrexate. These responses were seen as early as week one and sustained up to two years in the open label extension phase of the longest RA study.

Cimzia treated patients also experienced significant and clinically meaningful improvement in physical function, pain and fatigue again as early as week one and sustained for two years.

Cimzia plus methotrexate combination therapy inhibited radiographic progression to a greater extent than placebo plus methotrexate based on the change and the modified total sharp score, which is a validated measure of joint and bone damage. In addition to greater proportionate Cimzia patients had no detectible radiographic progression compared to placebo treated patients. These radiographic findings are important because evidence of x-ray changes correlate with worsening physical function and disease progression.

Another important measure of response and important to patients is work productivity. Based on a prospectively designed and validated work productivity survey administered as part of the phase 3 program, results showed that after one year of Cimzia therapy patients gained up to…

Jeff Graham: Please conclude your remarks.

Marc Jensen: …four days of work and 29 more productive work days compared to placebo. So in summary Cimzia has a unique structure, flexible dosing, it could be used as monotherapy, it induces fast and lasting improvement in RA signs and symptoms and inhibits radiographic progression. May I answer any questions?

Vyn Reese: Any questions from the committee? Thank you.

Marc Jensen: Thank you very much.

Vyn Reese: Up next is Dr. Jeff Peterson. On deck is Dr. Pam Sardo from Abbott.

Jeff Peterson: Good evening…or good morning I should say. I'm Dr. Jeff Peterson. I'm a rheumatologist and I'm the managing partner at the Seattle Arthritis Clinic, a group of six rheumatologists and I'm president of the Washington Rheumatology Alliance which represents 26 of the roughly 70 rheumatologists in the State of Washington, so about one-third. I'm here representing the WRA primarily because we believe that access to medications is the key and committees such as what you're representing today put limits on what our patients are able to access. I wanted to point out that you as a committee are relying on the pharmacists who are the PharmDs to present a bunch of data to you on a bunch of studies that don't necessarily represent what happens in real life.

Study patients are not clinical patients; particularly in slide 11 here I see a comparative effectiveness of etanercept versus infliximab. I've not seen this data until this morning. But I did want to point out to you that as far as I know there's been no good random controlled studies of any comparisons between the TNF agents and yet I think there were three or four mentions of studies. I'm sorry, yeah, I think I would be the one who would know. So be really careful about what you hear from your pharmacists about what is happening with the patients. I really think that you as committee members should be listening to the doctors who treat

these patients and the ones who deal with them every day as to what works for patients. I don't think…and there's a huge difference between the TNF inhibitors as far as rheumatoid arthritis but there's a definite difference between psoriatic arthritis. I think etanercept is far less effective, far less effective and you have to use twice the dose to get the same effectiveness through the skin yet this committee last year recommended it being used solely. I disagree with that completely.

I think in certain circumstances using infusibles is a very good appropriate action. It can be cheaper by quite a bit if it's a small person—two vials of infliximab is about half the cost of etanercept. So I think you have to give the doctors some choices here and let us decide what's best for the patient and best for the community. And that is all I have to say.

Vyn Reese: Thank you. Dr. Gartlehner is an M.D. who reviewed this. Okay? And would you like to comment on the last speaker?

Jeff Peterson: I actually would love to hear some comments from the…

Vyn Reese: Gerald, are you still up?

Gerald Gartlehner: Yeah. Regarding the evidence on etanercept and infliximab there is actually open label RCT, one other randomized trial and four prospective cohort studies that compare the two and the citations are in our report. It's not good evidence, but it's the best…

Jeff Peterson: But you're not understanding. You're just giving bad evidence or not good evidence and these people don't know. They're relying on you to make a decision and you're telling them, "Hey, this is really important stuff, but oh by the way the data is not that good." And in my hands as a practicing physician I treat patients. That data is completely wrong and you're telling them, this committee, who doesn't know that, you know, based on bad evidence that they're to make this decision and that's what I disagree with and I think the committee needs to know.

Vyn Reese: You know, his job is basically to look at the studies and if it's low evidence the committee, you know, regards that as not much evidence at all and probably would be discounted. So I wouldn't be…the committee is not without a mind of its own. So if that evidence is poor…

Jeff Peterson: I understand that too.

Vyn Reese: His job is to bring the evidence forward and it's our job to decide whether it's enough evidence to make a decision.

Jeff Peterson: As a practicing physician we try to care for our patients. Let us do what we do best.

Vyn Reese: Okay. Next up is Dr. Pam Sardo of Abbott. On deck is Dr. Carrie Johnson of Amgen.

Pam Sardo: Good morning and I would like to thank the committee this morning for the opportunity to speak about Humira and I also want to thank the committee and the OHSU DERP team for allowing input to the draft documents.

Humira is directed against inflammation that is seen in rheumatoid arthritis and psoriatic arthritis, ankylosing spondylitis, Crohn's disease, psoriasis and juvenile idiopathic arthritis. These are the six FDA approved indications that Humira has. So Humira does have the most FDA approved indications of the self-administered injectables.

Regarding safety – there are multiple comments about safety in the DERP review and all of these agents should be monitored by prescribers. In the Humira clinical trials patients treated with Humira the safety profile was consistent and similar with the safety profiles seen in patients treated for rheumatoid arthritis and the DERP review does provide information that long-term safety information is missing, on page 104 for certain agents and I did want to comment that Humira has been studied in clinical trials for 12 years and has a large clinical trial safety database. The safety database alone contains information on over 19,000 patients in over 25,000 patient years of exposure.

Rheumatoid arthritis in a study published in Arthritis and Rheumatism I did one to bring to your attention that patients who received Humira and methotrexate did achieve significantly greater improvement in signs and symptoms in their ACR scores and degree of disability compared to methotrexate and placebo.

In an open label extension study Humira and methotrexate did continue to inhibit the joint damage progression for up to five years. In the juvenile arthritis indication 94% of the patients stratified were pediatric ACR 30 responders. In Crohn's disease there was a charm study that looked at clinical remission and significant patients 40% and 36% in the Humira arm did achieve clinical remission at 6 months and 12 months and also indicated on page 63 of the DERP review there is additional information about lower hospitalization risk with Humira. There's a study about that. And in the GAIN study there was information about the safety and efficacy of Humira in patients who were initially treated with Infliximab and lost response or discontinued based on intolerance. In those patients outcomes were also described.

In summary I did want to thank you for your consideration of Humira for the appropriate patients in Washington and I would be happy to take any questions that you may have. The committee is encouraged to review this full comprehensive safety and efficacy indication in the prescribing literature. Thank you very much.

Vyn Reese: Thank you. Any questions from the committee? Okay. Up next is Carrie Johnson from Amgen. On deck is Greg Gardner from the University of Washington.

Carrie Johnson: Thank you for the opportunity today to speak in support of Enbrel, a product that now has over 17 years of collective clinical trial experience and over 2 million patient years of post marketing exposure. I'm Carrie Johnson, a PharmD and Medical Liaison with Amgen and I'm requesting that you maintain the current PDL status for Enbrel. In the next few minutes I'll highlight five key attributes of Enbrel which make it unique among the TNF inhibitors.

The first is mechanism of action. Enbrel has a unique mechanism of action among the TNF antagonists. It's still the only fully human soluble TNF receptor [inaudible] antibody and as such has not been shown to cause cell lysis or induced neutralizing antibodies. It mimics the effects of naturally occurring TNF receptors.

Two is its indications and long-term experience. Enbrel has a broad scope of indications crossing both rheumatology and dermatology. They include rheumatoid arthritis, psoriatic arthritis, psoriasis, ankylosing spondylitis in

pediatric patients for juvenile idiopathic arthritis for which it is indicated for use in children down to two years of age.

Enbrel has 10 years of continuous safety and efficacy data in RA and JIA. It has over seven years in psoriatic arthritis and spondyloarthropathies and over five years in psoriasis.

Efficacy – Enbrel provides rapid and sustained long-term efficacy in moderate to severe plaque psoriasis with now publication of over 132 weeks of data in that setting. Enbrel has demonstrated sustained clinical responses in patients with RA through 10 years at a stable dose. In fact, there's no labeling allowing for increased doses of Enbrel in RA or other rheumatologic conditions. Enbrel, in combination with methotrexate has demonstrated three years of halting radiographic progression in RA patients.

Importantly, in psoriasis clinical trials following withdrawal of Enbrel for up to five months re-treatment was effective and well tolerated with the majority of patients recapturing their initial response, which is important in a setting where drug can be intermittent.

Fourth, we just published our data in psoriatic arthritis with a primary end point looking at the skin. It's the first psoriatic arthritis trial looking with a primary endpoint of skin response. Enbrel achieved mean posse responses in line with other therapies in that setting, psoriatic arthritis.

Safety – the final consideration. Rates of serious adverse events and serious infection over the past 10 years have remained low, stable and not significantly differently from placebo or methotrexate. Unlike some other anti TNF agents there's no increase in serious infection or overall malignancy in patients treated with Enbrel compared to patients treated with control. Importantly, as well, unlike some other anti TNF agents there's no difference in the incidence of serious infection or malignancy in patients younger than 65 or older than 65.

Additionally, some large European registries of rheumatoid arthritis patients have now separated Enbrel out from monoclonal antibodies based on mechanism of action and these registries have fully published data now showing differences from Enbrel and the monoclonal antibodies in terms of herpes…

Jeff Graham: Please conclude your remarks.

Carrie Johnson: Additionally, one other unique properties is it's short half life of 4.3 days. Double that for the monoclonal antibodies. In conclusion, Enbrel is unique among the TNF antagonists, has over 17 years of collective clinical trial experience and over 2 million patient years of post marketing exposure. Rates of serious adverse events have remained low and stable over time and other than injection site reactions, not significantly different from placebo or methotrexate. Thank you.

Vyn Reese: Thank you. Up next is Dr. Greg Gardner from the University of Washington. On deck is Dr. Ben Goffe.

Greg Gardner: Well thank you committee for the opportunity to say a few words. I also want to commend the reviewer for the review done on these agents. It's difficult literature to go through and you did a very admiral job.

I'm a Professor of Medicine at the University of Washington and I split my time between Harborview and the University of Washington. I'm really here to represent my patients; many of whom are Medicare covered. I've been a rheumatologist now for 21 years and I trained in the pre-biologic era. I can tell you my rheumatology clinic as a fellow was full of people with rheumatoid arthritis in wheelchairs, Felty's syndrome, rheumatoid vasculitis, those things are now anomalies for my fellows. They rarely see those things anymore. Just to give you an idea of the power of these new agents; I tell my patients, "If you respond to these agents you'll never know how sick you could be." It's been an amazing transformation as I've seen the pre biologic and the biologic era. If you would have told me 21 years ago when I was a fellow that 50% of my patients could go into a clinical remission with their rheumatoid arthritis I would have been incredulous. These have been a major advance in the treatment of my patients. In fact, I remember as a fellow there was an editorial that came out that said, "What we need in rheumatoid arthritis are drugs that statisticians don't have to tell us that they work, that patients tell us they work." And it's come true. It's been an amazing run for us as rheumatologists to see these drugs work.

I would also urge the committee, if possible, to make the preauthorization process as easy as possible. My poor nurse spends a lot of time on the

phone trying to get these drugs approved. The other advantage of the biologic agents, I will point out in conclusion, is if you look at methotrexate in many patients it does work, but for many of those patients the disease continues to progress whereas with a biologic agent even though you may have an incomplete clinical response bone and cartilage is protected. Thank you.

Vyn Reese: Thank you. Any questions from the committee? Next on the agenda is Dr. Ben Goffe. On deck is Fred Sego from Ortho-Biotech.

Ben Goffe: Well thank you for allowing me to speak this morning and I think almost everything I wanted to say has been said, but I'll reiterate. I'm here on behalf of my patients and myself to ask the committee to consider parity access for all the targeted immune modifiers or biologic drugs as we call them, but primarily adalimumab and etanercept for psoriasis and psoriatic arthritis. I originally trained in internal medicine at the CDC in Atlanta as an epidemiologist. I switched to dermatology in clinical research over 40 years ago and have concentrated on psoriasis beginning with PUVA in 1974. I'm a clinical professor at the medical school and teach the course on psoriasis and Phil Mease and I did the first study of a biologic drug, etanercept in psoriasis and psoriatic arthritis in 1997, which was published in The Lancet in 2000. I've been following some patients on etanercept as well as another less used drug, alefacept for over 10 years and since then I've participated in some of the phase 2, but almost all the phase 3 and phase 4 studies that currently use biologics for psoriasis and psoriatic arthritis. I began using adalimumab in 2002 and it was not approved for psoriasis until 2008. With this background of using etanercept, adalimumab, alefacept and infliximab, the recently approved new [inaudible] and the yet to be approved ABT874 as well as efalizumab, which is now unavailable. I feel a position to justify having all of these options available to me and for my patients. I should also include golimumab in this group. I've used it but it's normally not available to dermatologists.

A particular patient may have a priority for safety or speed of onset or emphasis on psoriasis or arthritis or have contraindications such as [inaudible] for lupus or demyelinating disease or congestive heart failure, which would lead me to one or another of these drugs. There's almost 2 million patient years experience with etanercept; almost a million patient years with adalimumab. The safety and efficacy of these drugs, as you've

heard before, has been remarkable especially when compared to the alternatives such as methotrexate, cyclosporine, psoriatin or cellcept.

I feel that well trained rheumatologists and dermatologists are very capable of these rational decisions thus I'm respectfully asking you as I have in the past to allow us parity access to adalimumab and etanercept as well as all the other biologic drugs, which we feel are appropriate for a given patient. Thank you.

Vyn Reese: Thank you Dr. Goffe. Any questions from the committee? Up next is Fred Sego. On deck is Dr. Michael McDonald from Bristol-Myers Squibb.

Fred Sego: Good morning. Fred Sego. I'm the Principal Scientific Liaison with our Health Outcomes Group with Centocor Ortho-Biotech here to talk about infliximab and if there is any time [inaudible] but I doubt it. Basically used to…infliximab was the first approved TNF inhibitor approved in 1998 and is indicated for the use in plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, pediatric Crohn's adult fistulizing, Luminal Crohn's, ulcerative colitis as well as the only infused [inaudible] approved for first line biologic use in rheumatoid arthritis. We have experience with over 1 million patients worldwide with infliximab.

In the rheumatology space the clinical data in phase 3 trials for infliximab supports the clinical strength of Remicade with ACR20 scores of up to 62% with consistent structural damage data supporting significantly less progression of structural damage compared with methotrexate alone, as well as a great proportion of patients with no progression of structural diseases measured by Vandra [inaudible] Sharp scores of less than or equal to 0.

As well, the START trial data support consensus utilization analysis for infliximab with about 70% of the patients achieving clinical goal at 3 mg/kg as well as only about 18% of patients requiring another dose titration to 4.5 mg/kg to achieve clinical goal. So approximately 90% of patients achieve goal at that dose. The safety profile, you've seen the analysis, is consistent with those of the class as reflected by label inclusions. One of the things that was remarked by the speaker regarding safety is that there really is a lot of variability between trials comparing these in a comparative effective analysis requires the look at when these

trials were done, the patient populations within those, disease state severity, etc.

In January of this year the…just last month the [inaudible] of Rheumatology Disease published a consensus statement by international thought leaders in rheumatology basically stating specifically "There is no evidence that any one anti TNF blocking agent should be used before another one can be tried. There is also no evidence that any TNF blocking agent is more effective than any other NRA". They distinguish various factors in that analysis including a need to assess each patient individually, the clinical and lifestyle factors of the patient and the benefit and risks of the biologics including concomitant therapies. As well the need for deference and providing choice based upon persistency data, switching and as well as the variability of the disease in each patient with respect to disease state severity and route and administration.

One of the things that I know is published in both manuscript and abstract form is a lot of data based upon claims and utilization analysis and persistency. I think that's a very important factor to assess when you're looking at these products. For infliximab there's very strong data supporting persistency as a result of the infused products compared to the subcutaneous or injected products.

The data analysis of biologic use in RA supports clinical findings in phase 3 trials clearly showing that at best only half the patients initiated on one biologic therapy for RA continues on that agent and that upwards of 30% have tried two or three other anti TNLs.

Jeff Graham: Please conclude your remarks.

Fred Sego: We are here to represent choice in the portfolio for biologics and anti TNFs in the use of RA and other biologic diseases. Thank you very much.

Vyn Reese: Thank you. And the last stakeholder is Dr. Michael Maldonado from Bristol-Myers Squibb.

Michael Maldonado: Thank you. I'm Michael Maldonado. I'm a rheumatologist with Bristol-Meyers Squibb in the U.S. Medical Group. Bristol-Myers Squibb actually supports comparative effectiveness efforts like the DERP. I'm here to support Orencia, abatacept for infusion, which is indicated for the

treatment of moderate to severe RA and juvenile idiopathic arthritis, polyarthritis for ages 6 and up. The DERP captures the indications correctly. The clinical trials that support the effectiveness, safety and quality of life data is also appropriately captured in the DERP. We think the breadth and depth of this data supports the preferred status for abatacept in the preferred list in Washington. Thank you. Any questions?

Vyn Reese: Thank you. Any questions from the committee? Thanks. Okay. I'll now open it up for discussion. One change I can see right away is that…

Jason Iltz: Is Gerald still on the line?

Vyn Reese: Gerald, are you still on the line?

Gerald Gartlehner: I'm still on line, yes.

Vyn Reese: Okay. There might be questions during the discussion so I would like you to remain on the line in case something comes up and we need your input on.

Gerald Gartlehner: Okay.

Vyn Reese: One thing in our drug list is one of the drugs has been taken off the market. It's efalizumab and that needs to be stricken from our list there. that's a drug that's no longer offered. As I understand, Gerald, the new drug simponi is not…you did not have a chance to review that. Is that correct?

Gerald Gartlehner: This is correct, yeah.

Vyn Reese: Okay.

Jason Iltz: Gerald, this is Jason, part of the P&T Committee meeting. I just had a question for you that follows up our second to last speaker who pointed out that in his estimation there's really no way to tell when you look at a specific patient, you know, which medication do I choose? Which one's gonna work for them. And while it may make sense based on the patient that's sitting there to choose, you know, one of a few, you know, in terms of efficacy when you look at the studies are you sort of seeing that as well that, you know, some of these medications while there's a lot of

overlapping in FDA approved indications that, you know, one doesn't always stand out above the other in the study groups that have been included in these designs?

Gerald Gartlehner: Yeah, I would agree. I don't think with the current evidence you cannot really predict which one works best as a first line treatment. They all seem to work pretty well, but not all people then, again, respond when…I don't think it's possible to really foresee who are the responders and who are not.

Jason Iltz: Thank you.

Vyn Reese: I have a question for Medicaid. The way these are handled now, is there just one drug in each class? What are the speakers talking about how difficult it is to get drugs and to get authorization for some drugs? Do we just have one drug for each disease state or one IV and one subcutaneous? Or not? Can you explain the formulary to us now?

Siri Childs: Right. This is Siri speaking for Medicaid and we have a list of preferred drugs – Enbrel, Humira, someone could help me. Maybe you could turn to your list of preferred drugs. All of them require EPA. Even if they are preferred they require EPA so that they're used for the correct indication, the correct studied indication by the specialist for the right dose, for the right dosing frequency. So that's what they're talking about. We try to use them according to the FDA labeling.

Vyn Reese: Okay. So I understand it. So even though they're on the PDL they still require…

Siri Childs: Even they are preferred the preferred and the non preferred each require EPA to be used according to their FDA labeling.

Vyn Reese: Okay.

Jason Iltz: And this is Jason. I would support that continuation not only to make sure they're being used appropriately based on labeling, but these medications also have side effects and, you know, there is safety that needs to be taken into account as well. So I think that's absolutely appropriate. Anytime we have an EPA process, you know, I don't think that the restrictions on these are anything that aren't in place through an FDA standpoint from a safety

and a dosing and a monitoring situation. But it just takes time. The phone call itself takes time. And so even though there's only a few things that you have to meet in order to get these medications it's just…it takes time from that standpoint.

Patti Varley: This is Patti Varley. Can I clarify that part of that EPA would be including that medications used in children are approved for use in children. Correct?

Siri Childs: To answer Patti's question for the record, the answer is yes. This is Siri.

Deb Wiser: This is Deb Wiser. I just want to clarify also how a preferred item on the list is handled versus one that is not labeled as preferred on the list.

Siri Childs: Well, a preferred drug with an EPA code which the pharmacist inserts indicating that it is the appropriate use will go through without a stop. A non preferred drug using the EPA criteria will stop and we pen to the doctor and ask the doctor, you know, for the appropriate use. Now if they've tried and failed a preferred drug then using the EPA code even a non-preferred drug would go right through.

Carol Cordy: This is Carol Cordy. This is kind of a bigger issue but in light of the drug efalizumab that was taken off the market, we have been…have tried to use the term safe and efficacious, but in the past few meetings there have been some medications that aren't really that safe and we've kind of removed safe and just said efficacious and we've never really looked into that as what makes something safe enough or not safe and this is a group of drugs that has, as Jason's mentioned have a lot of side effects. And some of those aren't particularly safe. So it's just kind of the bigger philosophical issue is what is safe and how do we…

Duane Thurman: This is Duane Thurman. I think that the low level is the FDA approval that, you know, it is safe. I think that you can…I don't think that you could make a statement that they are unsafe as approved, but I think you can make no statement on safety as part of your deliberations.

Vyn Reese: This is Dr. Reese. These are high risk, high reward drugs. So they're not, you know, prescribe them without a good indication. So we could just strike safe from this.

Carol Cordy: Yeah.

Vyn Reese: Because they certainly have killed a few people.

Jason Iltz: This is Jason again. As I look at this, you know, one of the things that I guess I'd ask the committee on is there's a statement in the middle here that seems to sort of cloud the issue where we're trying to pick and choose medications based on their FDA approved indication and making sure that they're all listed on there and I think it's a little redundant. There's at least three medications that we've reviewed that have six or seven of the indications and as we've heard it's tough to figure out which one is better when you have a patient sitting in front of you or which ones they will respond to. So I guess my recommendation would be that we sort of remove that part where it says, "Must include a drug approved for treatment of each immunological condition for which they have FDA approved indications". We're already really making sure that's happening through the EPA process anyway. And so rather than to, you know, put a medication on the list; for example, I think it was ulcerative colitis that really didn't have any data. Rather than make us choose one to be preferred seems a little silly to me and a little redundant from the indication standpoint. So my recommendation would be that we take that sentence out of there and leave it similar in the rest of the wording but also then add that we support the continuation of an EPA type criteria.

Vyn Reese: So you want to strike the PDL must include a drug approved for treatment of each immunologic condition. You want to strike that long sentence?

Jason Iltz: Yeah, that whole long sentence. And there's multiple ones that are self administered.

Vyn Reese: Not the whole thing.

Jason Iltz: Not the…

Vyn Reese: Just PDL. When you say PDL about halfway down.

Donna Sullivan: I understand.

Vyn Reese: Okay.

Carol Cordy: This is Carol Cordy. If we're changing the wording here I think the sentence before that should say no single instead of no other. Isn't that supposed to…

Vyn Reese: No single, yeah.

Jason Iltz: Do you want to remove safe as well?

Carol Cordy: Yes, and remove safe unless people want to keep that in.

Vyn Reese: No. Anyone want to keep safe in?

Jason Iltz: And then this is Jason. The only other addition that I would make would be prior to the last sentence about therapeutic interchange and if we said something to the effect of, "These medications should continue to be subject to EPA criteria that guide their appropriate use".

Vyn Reese: Now before we had a section about…that should include a self-administered agent as indicated. We're going to strike that whole…we're not going to talk about which ones to add. My understanding is the intravenous medications are more risky than the subcutaneous ones. And that's been shown in several trials and the administration reactions can be quite severe. So if there is a drug in the same class it seems reasonable to use the self-administered drug first, but I don't want to guide the process that closely though. But clearly the subcutaneous drugs are safer.

Donna Sullivan: This is Donna Sullivan. I…with the Health Care Authority. I just want to remind the committee that this preferred drug list is used for not just Medicaid but also for two plans that are administered through the public employee's benefit board and we don't do EPA. So you can't really put that into the motion as part of the P&T Committee. That would be I think a function of the DUR board to allow Medicaid to do EPA on this drug class.

Vyn Reese: Okay. Thank you.

Siri Childs: This is Siri and you could put it in the motion if you indicate that it's for Medicaid.

Jason Iltz: I would be fine with that amendment.

Duane Thurman: This is Duane Thurman. I want to caution the committee not to sort of micro manage the language to start separating out the individual agencies. I think that the issue we're trying to deal with here is how do we ensure that all of the FDA approved indications are represented on the Preferred Drug List? And as you know our next step is to take your motion and within those parameters select those drugs based on our cost experience. And so I think you need to take a higher level to say…I don't think you can just rely on the EPA. I think you have to say what it is we need to have as part of the class and then let us do the analysis based on that. I think that any of the…I think you can assume that the EPA criteria will follow the FDA indications, but I think it would be a clearer statement to stick with the actual indications rather than just use a blanket EPA statement. I don't know if that's helpful or not helpful.

Patti Varley: This is Patti. I was feeling uncomfortable too with the idea of sort of what is our intent? I guess I want to get back to what the intent is here. And in listening to the shareholders and, you know, the intent is that medications are started with the appropriate medication for the appropriate condition, which is based on the FDA approvals with the understanding that if those first line drugs of choice that are available are not efficacious for that individual then the clinicians are allowed to move on to other agents. So if that's the intent then as long as we have treatment available for all conditions that have FDA indication, including specific disorders as well as age, as well as root, that to me is really what I would like this to state. And I think that would then cover the different agencies allowing for within those agencies that intent to be carried out. I'll certainly take feedback about that, but that's sort of my thinking.

Vyn Reese: I'd like to excuse Gerald right now. He's still hanging on I think. Gerald, I think we're safe to let you go.

Gerald Gartlehner: Okay.

Vyn Reese: Thank you.

Gerald Gartlehner: You're welcome.

Vyn Reese: All right. Thank you very much. We're now crafting these lengthy wordy documents. So what you're saying is that you wanted the previous

statement back in? The PDL must include approved treatment for each immunologic condition? That's what you're saying. So you want to put back in the stricken section.

Patti Varley: Right.

Vyn Reese: And also it should include a self-administered agent if indicated. Right?

Patti Varley: Right. And I just felt like, again, this is Patti Varley, that that really was our intent, which is appropriate access for appropriate use. I think the different agencies handle these things differently, but what we want each agency to do is to have accessible medications for these specific disorders that are FDA approved and ways of that agent for both administration type, as well as populations, i.e. pediatrics, etc. So that to me would cover what I think would be appropriate. I think that these should not be subject to therapeutic interchange because of the individual responses and I do think that, you know, because there isn't, from the evidence provided, there isn't a way to look at a patient and say, you know, "You definitely would respond to this agent or this agent". That there are FDA guidelines about disorders and which one might be best for a person, but you also are wanting it to be where if that one doesn't work for an individual they can move on to the alternatives, which is what all the experts were saying they do. I think what the guideline would be is the different agencies would list, in whatever way they do, where do you start and where do you go from there?

Duane Thurman: Yeah. This is Duane Thurman. Just to clarify, you know, I think that the…we need to stick to the therapeutic interchange whether it's permissible or not with the preferred status and understand that the three agencies have very different benefit structures. I think the other thing to keep in mind is under the endorsing practitioner status that there won't be a situation where you absolutely cannot get the drug. There are dispense as written overrides. This is simply the preferred drug and it's giving us direction on how to best set up those preferred drugs. And I think underlying that you have to remember that we will be considering the FDA indications. And this is a particularly difficult class because of the multiple drugs with different indications and it's growing.

Patti Varley: Patti again. I also think just in looking at this review is the issue is sometimes as we know these drugs get released and then the side effects

are found out later. So the safety data continues to come in on many of these, which is why one was eliminated.

Vyn Reese: This is Dr. Reese. One other thing if we're crafting this motion is we need to add the two new drugs that were reviewed. They're not in this motion at all and they should be in the motion too. There's good data that those drugs…they have FDA indications now too. Those two drugs should be in there.

Jason Iltz: There's more than just two missing from the list.

Donna Sullivan: What else is there?

Jason Iltz: The third one from the bottom is not on the list and the anakinra is not on the list.

Donna Sullivan: And you want both of those?

Vyn Reese: We want the drugs on that list to go over to that list. Those drugs have all been reviewed and one has been taken…we already omitted the one that has been removed from the market.

Carol Cordy: This is Carol Cordy. Now I'm looking at that sentence just above the one we put back in about no single…and I'm not even sure that's true. No single targeted immune modulator medication is associated with fewer adverse events. Is that true? I'd like to remove it if it's not.

Patti Varley: Well this is Patti Varley again. I think you're correct, Carol, that if you looked at the IV administrative one showed a much higher side effect profile and I think there was some data about differences.

Carol Cordy: I don't think it adds to the…I don't think it has to be there.

Vyn Reese: So you want to delete that? We're trying to get one sentence at least deleted from this, right? It's pretty hard. Let's delete that. Does anyone else want to leave that in there? I think there's an argument that they're not all the same as far as adverse effects in certain populations.

Jason Iltz: In pediatrics as well.

Vyn Reese: In pediatrics too.

Carol Cordy: And then take the caps off those new drugs.

Vyn Reese: Yeah, take the caps off.

Jason Iltz: Duane, can I ask a question to you of just clarifying something? I don't want to beat this issue anymore than we have, but my intent to delete the FDA approved indication was…which was said earlier to not micromanage the departments. And so let me just ask for clarification that when we use the word FDA indications that that is clear because some of these medications, while there might be multiple ones approved for RA for example they are approved for different levels of rheumatoid arthritis. And so, you know, when we say FDA indication are we just talking the general treatment of the condition or are we talking about a mild form, a moderate to severe form? What are we really talking about here? And that's what I was trying to get at by deleting that and just letting the department agencies sort of guide the preferred list realizing that all of these medications will be on the list, but some of them would be preferred.

Duane Thurman: I think that we're looking at the basic level of FDA indications. I think that the other, you know…and this is a very confusing class both, you know, for us when we take the next step to sort these out, but I think that you also have to rely on the fact that, you know, the treating physician is going to be aware of those also. So there's a lot of…there's also a part of the programs that don't want to micromanage how a treating physician uses the drugs. I mean an example is we can't prevent someone from using them off label, but in terms of the preferred status we're not going to take that into account. So I think it's in between. It does not go to that level of…go ahead Siri.

Siri Childs: This is Siri speaking for Medicaid and for what you are just saying is the very reason that we have EPA criteria for Medicaid because we do not want these drugs being used off label and being used in a manner which hasn't been studied to show its safety and efficacy. So that's why that particular statement is very supportive for the work that we're doing.

Duane Thurman: I guess just to summarize it, Duane again, is, you know, three levels. I mean you're doing…the FDA is doing a basic review. You are looking at the evidence and presenting your motion to us. The Department's also as

a part of their benefit design, build in, EPA and other criteria to ensure appropriate use of the drug and then on the final level the treating physician has the responsibility to the patient to use their knowledge to do it. And so I think that…that, you know, for the record it's clear that you are supportive of that appropriate. That is the approach that Medicaid is taking and I think the other agencies use their own similar approaches although not formally EPA and so I think that's the system and how it works out.

Christine Klingel: This is Christine Klingel. I just wanted to clarify to make sure when we're adding in the new agents…so we are adding them to the preferred list? Because I see here like abatacept is not preferred right now and it is being added to the motion. So we're saying that they are going to be preferred?

Donna Sullivan: This is Donna Sullivan. This is where there's a little bit of semantics that's makes this very confusing. We have the preferred drug list, which includes drugs that are preferred and non preferred. So by adding them to the motion in the past they have been deleted…I think omitted by the committee because of the evidence supporting them. For whatever reason they were not included in the motion. Now they want to be included in the motion. It just means that they will be included in the cost analysis now and they are eligible to become preferred based on their FDA indications.

Christine Klingel: Thank you.

Vyn Reese: Are we ready for a motion now? Are people satisfied with this complex motion as written?

Carol Cordy: Yes. I'll speak for myself.

Vyn Reese: Okay.

Carol Cordy: I think it looks fine. This is Carol Cordy. Can we not read the whole thing and can I just make the motion as it's…

Vyn Reese: Better read it.

Carol Cordy: Better read the whole thing? Okay. After considering the evidence of safety, efficacy, effectiveness and special populations for the use of targeted immune modulators for the treatment of immunologic conditions

for which they have FDA indications, I move that…can I not pronounce all those? That those drugs…does somebody else want to pronounce them for me?

Vyn Reese: Etanercept, adalimumab, abatacept, rituximab, certolizumab, natalizumab, alefacept, anakinra and infliximab.

Carol Cordy: Are efficacious. The PDL must include a drug approved for treatment of each immunologic condition for which they have FDA indications (rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, Crohn's disease, ulcerative colitis, and plaque psoriasis) and should include a self-administered agent if indicated. These medications cannot be subject to therapeutic interchange in the Washington preferred drug list.

Man: Vyn, can I make a comment?

Vyn Reese: Sure.

Man: Juvenile rheumatoid arthritis isn't used anymore. It's juvenile idiopathic arthritis.

Vyn Reese: Okay. So why don't we strike rheumatoid and put idiopathic. Is that agreeable to the motion maker?

Carol Cordy: That's agreeable.

Patti Varley: This is Patti Varley. I just want to clarify and should include a self-administered agent. Aren't pills self-administered? Are we talking about injectable?

Vyn Reese: Yeah, these are all injectables. Some are IV and some are sub-Q and one is IM.

Patti Varley: So why is…okay. So that's why I'm…

Vyn Reese: In some indications there's both an IV and a sub-Q that are…that have the indication but the sub-Q is safer in general.

Patti Varley: Okay. So it's intended for the sub-Q versus IV?

Vyn Reese: Right.

Patti Varley: Okay.

Vyn Reese: Any further discussion? Can we have second?

Deb Wiser: This is Deb Wiser. I second the motion.

Vyn Reese: Okay. All those in favor say, "Aye".

Group: Aye.

Vyn Reese: Opposed, same sign. Motion's passed. So now we have a brief break. We convene here in about 15 minutes.

Vyn Reese: This is Dr. Reese and the next item on our agenda is the drug class review scan on asthma controller drugs and it's Megan Van Noord. Is that correct?

Megan Van Noord: That's correct.

Vyn Reese: Okay. Why don't you go ahead. Our first slide is up.

Megan Van Noord: Okay. You have the slides in front of you?

Vyn Reese: Yes.

Megan Van Noord: Okay. Great. So this is the drug class review on controller medications for asthma and this is the first update and the first scan report. The last report was completed in November 2008 and included searches through April 2008. Next slide.

Populations included pediatric or adult outpatients with persistent asthma. Next slide.

And included interventions are inhaled corticosteroids, long-acting beta-2 agonists, leukotriene modifiers, anti-IgE medications as well as combination products. Next slide.

Efficacy and effectiveness outcomes include asthma control; quality of life; ability to participate in work, school, sports or physical activity; adherence; emergency department urgent medical care visits; hospitalizations and mortality. Next slide.

Harms outcomes are listed on slide six and I can give you a moment to review those. Okay, next slide.

To identify relevant citations we searched PubMed from January 2008 through December 29, 2009 and we also searched FDA and Health Canada websites for identification of new drugs, indications and safety alerts. Next slide.

For the study selection one reviewer assessed abstracts of citations identified from literature searches for inclusion. Next slide.

Searches resulted in 154 new citations. Of those, there are 29 new potentially relevant studies which can be found in Appendix A of the scan update. Next slide.

One new drug was found – ciclesonide, which was FDA approved in 2008. And our search found an additional seven trials evaluating ciclesonide, which were not included in the 29 above. Next slide.

So the next three slides go over safety alerts. Slide 11 discusses leukotriene inhibitors. The FDA has requested that manufacturers include a precaution in the drug prescribing information about neuropsychiatric events. You can take a moment to read that whole slide over because it's pretty lengthy. Okay. Let's move on to slide 12.

Slide 12 includes early communication from the FDA about an ongoing safety review of Xolair. The FDA is not recommending any changes to the prescribing information for Xolair and is not advising patients to stop taking Xolair at this time. They're waiting for results from the EXCEL study, which may suggest a risk of cardiovascular and cerebrovascular adverse events. I did check clinicaltrials.gov but an estimated study completion date for the EXCEL study is not yet available.

Okay. And the last safety alert is from Health Canada and it basically reiterates the information from the previous slide about Xolair from the FDA.

So that concludes the scan on asthma. Were there any questions?

Vyn Reese: This is Dr. Reese. I just had one question. So you haven't had a chance to really review the literature on ciclesonide, the new drug?

Megan Van Noord: That's correct.

Vyn Reese: Okay. That's not included in this report.

Megan Van Noord: Right.

Vyn Reese: Any questions from the committee? I'll take a motion to accept the scan.

Carol Cordy: This is Carol Cordy. I move to accept the scan.

Vyn Reese: I'll take a second.

Ken Wiscomb: This is Ken Wiscomb, I'll second.

Vyn Reese: All those in favor say, "Aye".

Group: Aye.

Vyn Reese: Opposed, same sign. The scan is accepted. Okay. Now I'll take stakeholder comments. And the first stakeholder is Brent Waters and it says self. He's not with an agency or a group. And on deck is Dr. Song, also self.

Brent Waters: I'm Brent Waters. I'm a Registered Pharmacist in the State of Washington since '98. In community pharmacy since that time working at Lawry's Prescriptions in North Seattle. I am not associated with any pharmaceutical company. I'm here to be an advocate for my patients, my asthma patients. Not just mine, but those statewide as well.

As you know, most of our DSH patients have some sort of a handicap be it mental or physical. I'm not here to talk about the ingredients in these

drugs, but to talk about a delivery system that will help them to control their asthma better thus reducing the acute attacks. Some of these patients need a drug called Advair, which has a unique delivery system. This system allows them to not have to inhale in conjunction with the actuation of a metered dose inhaler, but to cock a system inhale which releases the medication into their system.

Among my patients I have an alcoholic and one or two with Parkinsonisms. These people have very poor control, before they went on Advair, because they couldn't function properly. They were shaking – whatever worked or didn't work. They were using too much of their rescue medication. Many times going to the ER which is expensive as we all know. They have reduced those visits though the overuse of their rescue drugs has dramatically increased. They have improved their quality of life and it also costs less DSHS less dollars in ER visits, extra drugs. And I just ask that you consider keeping this drug on the formulary so they can have a better quality of life and so we can save some dollars. Thank you. Any questions?

Vyn Reese: Thank you. Next up is Dr. Song. On deck is Meredith Zarling from GSK.

Ted Song: Hello. Hi. My name is Dr. Ted Song. I'm an allergist practicing down in Tacoma. I speak for drug companies, for GSK, Genentech and Meda Pharmaceuticals, but I'm here on behalf of myself, my patients and the two allergists that I practice with.

I want to share a story of a patient that I had. He's an 18-year-old male who was diagnosed with severe persistent asthma. He's been in and out of the emergency room for the last five times [years] and every time he goes to the ER he gets treated with oral steroids and gets tapered down and by the time I saw him his FEV1 was less than 59%. He was getting two nocturnal awakenings a week. And based upon the NHLBI guidelines he's at step four or five. So I prescribed him Advair and then I saw him back in a month. Again he had gone to the emergency room because he had exacerbation and when I asked him what happened he said, "My insurance did not allow Advair because I was supposed to be on an inhaled corticosteroid". And we know that's not true and that could have prevented him an ER visit.

So I got him on Advair this time through samples and then I was able to get his insurance company to approve it and he was on a medium dose Advair. He was doing really well and then he started to regress. So I increased the Advair. He did actually well again and then he started to regress again. So at that point, based upon the guidelines, I added leukotriene antagonists, didn't do much. I added anticholinergic as well. It didn't do much, but I wasn't going to do [inaudible] because in my training I never use it. I don't want to deal with the side effects. So at this point he was still getting exacerbations. So I decided to step up therapy to step six, which is additional Xolair, which is anti-IgE therapy. He met all the criteria based upon his age, serum IgE level. I skin tested him. He was highly allergic and I submitted it to the insurance company again and it got denied. I submitted it again, he got denied. By this time he has severe exacerbation. He went to the ER, got admitted into the ICU for two days. At this point I was kind of frustrated so I called the medical director of the insurance company. I actually told him about my patient and he agreed to let him have Xolair for six months. My patient's been on Xolair for five months and he's doing great. He's been on Xolair, Advair 550 and PRN Albuterol and he hasn't been to the ER once since then.

And so my coming here is to say please let me do my job. It's really difficult every time I get restrictions on what medicines I can or cannot use and every time I have restrictions it delays giving proper care to my patients, causes undue suffering for example for this patient, in addition he drives up costs because he was in the ICU for two days. So I think that would definitely help me as a practicing physician. In my practice the majority…I would say about 60 to 70% of my patients are moderate to severe persistent asthma. So they've been through all different medications. So I hope you give me the opportunity and finally I feel like…I did 11 years in the Army and I was a…

Jeff Graham: Please conclude your remarks.

Ted Song: Okay. And one of the mottos in the Army is you need to beg, steal and borrow in order to get things done. That's the way I feel like and I hope you'll help me out. Thank you.

Vyn Reese: Thank you. Next up is Meredith Zarling of GSK and on deck is Dan Manning from Merck.

Meredith Zarling: Good morning and thank you for the opportunity to speak to you today about Advair, discussing Advair HFA. As you said my name is Meredith Zarling and I'm a Clinical Pharmacist and a Regional Medical Scientist with GlaxoSmithKline. I'd like to present information in support of Advair on the Washington State Preferred Drug List. And I'm only going to highlight three key points.

The first point is the National Heart Lung and Blood Institute panel of experts, after careful review of the literature, issued very clearly defined guidelines on the management of asthma. According to the guidelines, for patients greater than 12 years of age who meet the criteria for moderate asthma it's recommended that patients initiate therapy at step 3 in which one of the preferred therapies is a combination of low dose inhaled corticosteroid plus a long-acting beta agonist. For a patient with severe asthma patient should initiate therapy at steps 4 or 5, which the preferred therapy is a medium or high dose inhaled corticosteroid steroid plus a long-acting beta agonist combination. Advair is the only combination product, which is available in three strengths with a choice of a low, medium and high dose corticosteroid. Advair can be used for patients whose asthma severity puts them at steps 3 through 6 on the guidelines.

Second, Advair 250 50 is the only combination product approved for the reduction of exacerbations in COPD. Results from two large replicate 12-month COPD studies showed a 30% reduction in moderate to severe COPD exacerbations with Advair compared to Serevent.

Finally, Advair discus is the only combination product with a pediatric indication and is indicated for children four years of age and older for the treatment of asthma. Advair is also available in both a metered dose inhaler and a discus device. In clinical practice settings significantly fewer patients handled the discus incorrectly versus metered dose inhaler devices. The most common metered dose inhaler error was failure to coordinate actuation with inhalation.

In conclusion, based on the data, the indications and the recommendations of national guidelines, Medicaid patients are best served if Advair discus and HFA are retained on the Washington State PDL. Thank you.

Vyn Reese: Thank you.

Meredith Zarling: Are there any questions? Thanks.

Vyn Reese: Thanks. Next up, Dan Manning from Merck. On deck is Lee Ding from Genentech.

Dan Manning: Good morning. My name is Dan Manning and I'm a PharmD with Merck Medical Affairs and I'm here to talk about Asmanex, which is mometasone furoate. It is an inhaled corticosteroid as Meredith talked about. ICSs are the foundation for asthma management. Asmanex comes in two strengths – a 110 and a 220 dose and it's also indicated down to four years of age. It also has a proven safety track record. It is a dry powder device, which is breath actuated. Therefore the patient does not require a spacer. It also has a dose counter on it, which counts down each time the patient uses it. And once it gets down to 0 the device actually locks out. So Merck would like to ask the committee to consider adding a dry powder inhaler onto the PDL that is also a once-a-day. Any questions?

Vyn Reese: Thank you. Last stakeholder is Lee Ding, Genentech.

Lee Ding: Hi. Good morning. My name is Lee Ding and I am a Medical Science Liaison with Genentech. Today I'm here to provide information about an anti-IgE biologic therapy, which is omalizumab or Xolair. So I will quickly review the mechanism or action of Xolair positioning of Xolair within the NHLBI guidelines and also providing an update on the Xolair PI package insert.

Xolair exhibits dual mechanism of actions. So Xolair blocks allergic response by binding to and disabling the antibody IgE that triggers the allergic cascade. Treatment with Xolair also down regulates the number of IgE receptors on [inaudible] on atopic patients. The 2007 NHLBI guidelines added immunomodulator as a new category of medication for asthma control. It classifies Xolair as an immunomodulator.

And now I will spend the rest of the time giving you an update on the Xolair package insert. In December 2008 Genentech and Novartis, which is our copromo…promoting Xolair partner. Some [inaudible] a supplemental biologic license application, which is SBOA to extend the indication of Xolair to include children ages 6 through 11 years. In December 2009, which is just a couple of months ago Genentech and

Novartis received a complete response letter from the FDA in which they did not approve the indication. So because of the pediatric following the Xolair PI has been updated with the current FDA regulation associated with a new format for prescribing information. This requirement applies to all new and recently approved medications.

So clinical trials in the children ages 6 to 11 years were added to the pediatric section of the PI. A new limitation, new section was also added stating that Xolair is not indicated for use in pediatric patients less than 12 years of age. It's not indicated for use in acute bronchial spasm and it's not indicated for other allergic conditions. However, there's no change to Xolair indication. Xolair remains indicated for adult and adolescent patients 12 years and above with moderate to severe persistent allergic asthma. So in summary given the NHLBI guidelines include Xolair as the only immunomodulator for consideration in step 5 and 6 for allergic asthma, the unique MOA targeting IgE, which is the center driver of allergic asthma. We recommend that the committee continue to have Xolair as a treatment option for patients age 12 and above. Thank you. May I take any questions?

Vyn Reese: Thank you. Any questions? Thanks. I'll now open it up for discussion of the committee. I have one question. I don't see the IGG, any IGG medications listed on our prior motions. Did we not have any motion for Xolair in the past? Because it's been reviewed.

Jaymie Mai: This is Jaymie. I think it was not added to the PDL at the time you originally reviewed it.

Vyn Reese: Right. But it's been reviewed. It is efficacious. It's definitely an excellent drug for very severe asthma. So we should have it available. There's also recent safety concerns about it however, too. So that's…it certainly should not be wide spread in its use given its expense and possible risks, but for selected patients it sounds like it is the drug of choice or one of the drugs in a complex regimen. So it probably should be on the PDL.

Patti Varley: This is Patti. Does it need to be on the PDL or just accessible like most things are that if a patient fails previous PDL listed medications and is needing that they can obviously get it. But does it need to be on the PDL?

Jeff Graham: This is Jeff Graham. Megan, wasn't this drug on our original review of controller drugs?

Megan Van Noord: Oh, you know, I wasn't here when that report was done. But I can find out and get back to you.

Vyn Reese: I'm pretty sure it was. This is Dr. Reese.

Jeff Graham: Yeah. I'm not sure why we left it out.

Vyn Reese: I'm not sure why it was left out. That's my concern is that…so.

Siri Childs: This is Siri speaking for Medicaid and we've handled Xolair in our regular prior authorization program. We have…I'm hearing that it was discussed at the last meeting of this drug class and we were asked to continue it outside the PDL.

Vyn Reese: Okay. So we reviewed it but then kept it outside the PDL for safety concerns and…is that the…so it clearly needs to have some sort of prior authorization activity directed at it. But it's definitely…it has indications. So it's kind of an odd orphan drug there.

Siri Childs: This is Siri again and for the physician that spoke earlier I would really like to talk to him and give him my personal telephone number. If he has problems getting Xolair through our program I would be happy to help you. We just ask that you meet the FDA criteria, which it sounds like you tried to do. So we…I don't believe that we've had, you know, excessive issues with access and I'd love to talk to you about that.

Vyn Reese: So how do you think we can best handle it in the future? I was concerned about that too as well. Is it better to keep it on the PDL with a prior auth automatically or keep it off with a prior auth? That's the way it's best managed. Okay?

Siri Childs: Yes, my…I'm not allowed to make a recommendation. But I do believe that keeping it separate from the PDL and having it require a prior authorization is the best way to handle it.

Vyn Reese: Go ahead.

Deb Wiser: This is Deb Wiser and I guess my question is, "What is the benefit of keeping out of the PDL when it's indicated in severe asthma?" I guess…I'm also new to the committee so I'm trying to understand the logistics there.

Siri Childs: Okay. This is Siri speaking again for Medicaid. When a drug is on the PDL it means that there…it's a list of drugs that this committee has reviewed and there is a list of preferred drugs and there's a list of non-preferred drugs. And the criteria for using a non-preferred drug is simply tried and failed the, you know, preferred drug. And we do have rules for an endorsing prescriber. An endorsing prescriber who has signed onto the program can write DAW and just have that particular drug. So it kind of…well, it doesn't kind of…it does give them an opportunity to access the non-preferred drugs without any sort of criteria. And we believed that there was safety concerns and so that's why we'd like to handle it in our prior authorization program.

Ken Wiscomb: This is Ken Wiscomb and by precedence we've done this with other drugs while they were waiting FDA action, you know, just to see what happens.

Vyn Reese: But this drug's already been approved by the FDA. But there also is ongoing new safety concerns about it. So it's a very murky situation. So it should probably have some PDA review on it, it sounds like. So this is a very complex motion, but I'd like for someone to start looking at these and making…we can actually just say that we reiterate…there's one new drug but it wasn't reviewed for this presentation so we can't really add ciclesonide. The other drugs have been reviewed before and as was said earlier we're going to keep Xolair in its own category given the current situation with Xolair. Would anyone like to launch into this? Basically you can just say, "My motion on long acting beta agonists is the same as the motion of October 18, 2009".

Carol Cordy: This is Carol Cordy. Can you, Vyn, maybe explain for our new members the difference between a scan and an update and what the process is?

Vyn Reese: A scan basically is a very brief look at a drug class or in this case a group of drugs and it's not a complete review like a new update is where you're looking at every drug all over again and looking at all the new drugs and reviewing them in detail. This one is looking at any new date, any new drugs and is much more…it's a shorter, more cursory look and scans are

used periodically to decide whether they need to have a new update, in my understanding. And so when something is scanned if they see there are new drugs or there's new categories, there's new activity in that area then a complete update is scheduled. Some classes remain fairly stable and don't change much. Other categories are rapidly changing and those categories with multiple new drugs and new indications, they're the ones that tend to come up for complete updates. Whereas ones that the drugs are the same old players and maybe different dosages they tend to be scans until something is happening in that drug class. In general that's the way it's done.

Ken Wiscomb: The only other thing I would add is that the reason we ask you to approve of the scan is that if you do not believe that it contains enough information for a recommendation then the next step would be to say, "No, we need to see a full update before we can do this". And we do try to use a full update when there's a new drug added to the class, generally.

Vyn Reese: Any other discussion or questions? Okay. Does anyone want to take on this group? No one is stepping up. I'll go ahead and do it myself. Okay. The first drug class is the long acting beta agonists and I'd like to reiterate the motion from February 18, 2009 as the current motion. And it's after considering the evidence of safety, efficacy and special populations for the treatment of asthma, I move that Salmeterol and Formoterol are safe and efficacious only when used in combination with inhaled corticosteroids. No single long acting beta agonist is associated with fewer adverse events in special populations. Long acting beta agonists can be subject to therapeutic interchange in the Washington Preferred Drug List for the treatment of asthma.

I'll also…I'll make just sort of a series of motions. On leukotrienes – after considering the evidence of safety, efficacy and special populations for the treatment of asthma, I move that montelukast, zafirlukast and zileuton are efficacious. Montelukast has been associated with a lower incidence of hepatic toxicity…that should be hepatotoxicity not a…it could be hepatic toxicity too…than zafirlukast and zileuton. Zileuton and zafirlukast shall not be preferred drugs on the Washington Preferred Drug List. Montelukast should be the preferred drug on the Washington PDL for adults and pediatric patients as FDA approved. Leukotriene modifiers can be subject…should be cannot be subject…should be…since we already are taking them…

Jason Iltz: But we want them to be able to substitute.

Vyn Reese: Oh, montelukast. Okay. Can be subject. I see. Can be subject. The other two are not on it since we can substitute montelukast for the others. So leukotriene modifiers can be subject to therapeutic interchange on the Washington Preferred Drug list for the indication of asthma. That's the motion of June 17th.

Inhaled corticosteroids. I'll basically reiterate the February 18, 2009 motion, which is in front of you. And then also under corticosteroid combinations that's also a February 18th, 2009 motion.

After considering the evidence of safety, efficacy and special populations the treatment of asthma, I move that fluticasone/Salmeterol combination and budesonide/Formoterol combination are safe and efficacious.

Now that's a new…we have a new combination product I think. That's basically it still. Yeah. Okay. So we'll leave it that way.

Carol Cordy: This is Carol Cordy. On the drugs reviewed arformoterol is not included in the paragraph there.

Vyn Reese: Aformoterol.

Carol Cordy: Aformoterol, arformoterol. Is it spelled wrong?

Vyn Reese: No.

Carol Cordy: No. It's there, but it's just not…

Vyn Reese: Is that in Canada, I think. I think it's not a U.S. drug.

Carol Cordy: Well, it says it's a prior auth. It is Brovana.

Siri Childs: This is Siri and maybe for the benefit of the new members I'll tell you just a little bit about the drug effectiveness review process. We do have Canadian members of that committee in Oregon that does these reviews. And so if there is a Canadian drug in that drug class they do study those drugs also. And I think that's the case here.

Vyn Reese: Yeah. And I don't think we have to add that to our motion since we don't have the drug in this country. Okay. And so the remainder of that motion is the same as the one from February 18th, 2009. So I'm going to move…make a motion for all those drugs.

Ken Wiscomb: This is Ken Wiscomb…

Vyn Reese: Any discussion?

Ken Wiscomb: I'm sorry to throw this out there at this point. I just was thinking back about our discussion about the targeted immune modulators where we essentially looked at a class of medications that had a variety of indications and had a variety of different methods of action and we tried to apply the motion to the entire group for all the indications based on FDA approval. And so then when I look at this, and I realize we're trying to support step therapy to the treatment of asthma, but I'm wondering if we could not apply the same principle here and have one motion for the entire class? And whether or not that would make it more difficult or less difficult for administration? Sorry. I was just thinking more about consistency as compared to…

Siri Childs: This is Siri speaking for Medicaid and it certainly would make it more difficult not only for Medicaid but for all of the prescribers. We do step therapy now to a limited extent. I mean you can direct us, but it will be difficult for us to do it across all of these drugs.

Jason Iltz: This is Jason. Ken, I think the difference here would be that the TIMs are sort of all lumped together in one representative class if you will whereas these they're sort of segregated by action and what exactly their ingredients are. So for asthma for example you have subclass of inhaled corticosteroid and a subclass of combination inhaled corticosteroids in the same class…

Ken Wiscomb: And I agree Jason. I just thought I would ask the question just as a point of order for consistency and how we put our motions here.

Jason Iltz: Yeah. I kind of like this because it also…when drugs are subject to therapeutic interchange it really helps clarify what we can specifically

interchange at the pharmacist level. So I would support leaving it as it is at this point in time.

Vyn Reese: Any other discussion on the motion?

Ken Wiscomb: In that case I'll second your motion.

Vyn Reese: Okay. All those in favor for…of these motions, please say, "Aye".

Group: Aye.

Vyn Reese: Opposed, same sign. Okay. This motion is passed.

Jeff Graham: Vyn, Duane has something.

Duane Thurman: Just going back to your initial…this is Duane…discussion on Xolair. We're looking at the transcript from the prior review.

Vyn Reese: Great.

Duane Thurman: And the issue…okay, where. Barak Gaster brought it up saying, "I think what we're saying is that after considering the evidence that there's not enough evidence to make a decision to make a decision to add the subclass of anti-IgE therapy onto the Preferred Drug List. There's only one agent which has somewhat of a niche use and so I'm saying there's not enough evidence for this to be a separate class and so this specific drug, Xolair, does not have a place on the Preferred Drug List because its class is not included." And then Donna asked, "But I thought it had been reviewed." Barak said, "Not much was found." Jason said it was included in the group, but there was very, very little information which was available and it really did not appear to be real positive. Thinking back to some decisions the bottom line is Barak Gaster made a motion, "After considering the evidence of safety and efficacy I move that there is not enough evidence to add the anti-IgE therapy drug class to the Washington Preferred Drug List." We have an unidentified member seconding that. Jason opens it up and that motion passed.

Vyn Reese: Okay. I think there's enough evidence it looks like to me based on what I've read. There's enough evidence it's indicated for severe asthma, but patients who would otherwise not be treated by anything else essentially.

So it's a very small subgroup of asthmatic patients that could benefit from that drug and there are clouds now about its safety. So I don't know whether we want to approach…change that or not. That's…I mean…it's for different reasons I'm reticent about it now. And also it shouldn't be the first drug somebody reaches for asthma. It's absolutely…it's a drug that has definite risks. But it's also a drug that a severe asthmatic might prevent hospitalizations and emergency room visits in patients who have been tried on everything else.

Patti Varley: This is Patti Varley again. My understanding is if we left it like it is that they would have gone through those steps of trying alternative agents first and that either they could DAW or PA for, if they weren't endorsing prescribers, they could request if a patient had failed all those other ones to access that. But that by leaving it the way it is, it is not out there for people to consider as a first line drug of choice is my understanding.

Duane Thurman: This is Duane. I think that that's the good analogy as a second line treatment and you've done that in other drug classes where you've excluded the entire class or particular drug.

Vyn Reese: So I think we may want to still keep it in the same place, but for different reasons. That would be my sense of what the committee is talking about currently.

Jason Iltz: And I think I'd agree, Vyn, that our sentiment is probably the same although the data that we're looking at today is the first time we've come back to look at this. Right? So from a scan standpoint I don't know that I see any additional data or anything in this review that would lead me to a different conclusion than Barak had made previously. My understanding is this is the data we should be looking at. Right, from the scan? And so the only thing I see is two slides that actually point to continued safety alerts and continued monitoring and while, you know, there is a place in therapy for this medication those safety alerts have been reemphasized after we've made the decision from the previous motion as well. So it's a lingering issue with this medication. So, you know, I guess the question is do we need to make a statement or a motion about this particular subclass of medications? And if the answer is yes then I think we can just simply say that, you know, after considering the evidence, you know, that this medication shall not be on the Preferred Drug List due to lingering safety concerns or maybe we don't even have to say that.

Vyn Reese: We don't have to say anything. We can just leave it where it is.

Jason Iltz: And is that an okay…

Duane Thurman: This is Duane. I think in terms of…because you're reiterating the previous motion I think that you leave things as they stand in the status quo. So I don't think an additional statement is needed.

Carol Cordy: This is Carol Cordy. I just wanted to clarify something that was said before about DAW. My understanding, tell me if it's right, is that if a drug is not on the Washington Preferred Drug List you can't DAW it. So it is a different process.

Duane Thurman: Well, you can DAW always, but you may have to go through more…

Carol Cordy: It doesn't just work quickly.

Duane Thurman: But I think Jason's point that, you know, the evidence you're looking at is contained in this update is correct.

Jason Iltz: So I guess where we're a little bit confused here is the fact that we don't have that previous motion that you just read to us in the documents today in our packet. So I guess what we would need to say, you know, to Vyn's point, we've only covered the four. So that fifth one that's sitting up there we would need to say the same thing, Vyn, that you had previously said before if you want to take on that motion that we would reiterate that motion.

Jeff Graham: That was…this is Jeff. That was not a motion. That was just discussion. There's no motion there at all.

Jason Iltz: I thought I heard the last part said it was moved and it was seconded as a motion.

Duane Thurman: That's correct.

Jeff Graham: Okay.

Jason Iltz: So we can just say to reiterate that. From what date was it?

Duane Thurman: Yes. And that was the February…

Jeff Graham: 18th.

Duane Thurman: February 18th, 2009 meeting.

Vyn Reese: So what was the motion precisely so we can see it?

Deb Wiser: This is Deb Wiser just while we're waiting on that I wanted to…I know this is after the fact of the motion. I want to clarify something on the inhaled corticosteroids. It states at the bottom fluticasone and budesonide must be preferred on the Washington Preferred Drug List and I just wanted to know…I had seen equal efficacy amongst the inhaled corticosteroids and what the background was on that.

Donna Sullivan: This is Donna Sullivan with the Health Care Authority. If my memory serves me correctly it's because those two products are indicated for use in children. But I would have to look at the transcripts to verify that.

Vyn Reese: I'm pretty sure that was it.

Deb Wiser: Okay. Thanks.

Vyn Reese: So what's the question now with the prior motion?

Jason Iltz: So at the February 18th, 2009 meeting Barak Gaster was the one that made this motion and we had approved it. It simply reads, "After considering the evidence of safety, efficacy and special populations for the treatment of asthma I move there is not enough evidence to add the anti-IgE therapy drug class to the Washington Preferred Drug List for the treatment of asthma." So that was the motion that was moved and passed. So, you know, as a committee would could certainly make amendments to that if we need to. But that was the one that was on the table from the 18th of February.

Vyn Reese: I would just say that because of…I think there is evidence that it is efficacious. There is evidence it is in severe asthma and it's on national guidelines. So there's evidence, but I would say because of safety concerns that we will not add it to the Washington PDL. I would modify

that. It's sort of academic since we're not going to do anything. But I think there is evidence that it's efficacious in select cases of severe asthma and there is also ongoing safety concerns. So I mean that would be…and there are more safety concerns than there were before.

Jeff Graham: This is Jeff. Is that from your…this scan? There's no evidence in the scan. And so I don't know if you can really say there is evidence elsewhere because this scan didn't say that.

Vyn Reese: No. It just said that there are ongoing safety concerns essentially.

Jeff Graham: Right. So I think…

Vyn Reese: They didn't say take people off of it, but they said there was…there is…there are…

Jeff Graham: So I think if you want to say there's efficacious…you haven't got a lot of information in this can to say that.

Vyn Reese: Right.

Jeff Graham: I do think that an update is coming along, a full update, in this next year, but not yet.

Vyn Reese: It will shine more light in this area.

Jeff Graham: Yes, it will.

Jason Iltz: And evidence, Vyn, is kind of a broad term here. I mean we're not talking about evidence of efficacious or evidence of…I mean evidence could mean that, you know, there's not enough evidence from a safety standpoint or evidence from a use in appropriate populations. I don't know. I just don't see anything today that would really compel me to be able to say or to contradict the previous motion that this board supported in what we saw today specifically. I don't argue that it's not appropriate in certain…but I just didn't see it presented today and that's what we have to make our decisions based on.

Vyn Reese: Okay. That's fine.

Duane Thurman: This is Duane. I think one thing that you can do legitimately looking at what's been presented to you in the scan and what you reviewed in the prior update is to simply say after considering the evidence of safety and efficacy and special populations blah, blah, blah…I move…

Vyn Reese: [inaudible] the drug class. That's why we're not adding it, but we'll just say we won't add it.

Duane Thurman: Just don't say anything. Just say that, you know, sight what you're doing and say, "We do not add this class to the PDL".

Vyn Reese: Right. That we simply just strike the…not enough evidence. I would just say we will not add the anti-IgE therapy drug class to the Washington PDL for the treatment of asthma.

Ken Wiscomb: This is Ken Wiscomb. It probably should be should not instead of will not.

Patti Varley: This is Patti Varley. There's one uncomfortableness with this, which for me is the issue of not at all. I'm wondering if there's a way to say for the treatment…how to clarify that we know it's not the first line drug of choice, but that in severe cases…I guess the way it stands now it feels weird to me to say it shouldn't be there at all because we all say that there are those rare cases in asthma, but it's not first line or…

Duane Thurman: This is Duane. I think that that would not be helpful to us and I think it's sort of getting into managing the non PDL drugs and the way that the agencies handle those. I think that what this statement does is you're not making any statement on the amount of evidence. You're just simply saying that you've reviewed this and I think the message it sends is we need to know more about this drug class. We are going to do an update, but as it stands I think this is pretty clear to allow the agencies to do what you're talking about.

Vyn Reese: So it's going to be possible to get the drug for those patients who really need it.

Siri Childs: Absolutely.

Vyn Reese: But it's not going to…they are going to have to be jumping through some hoops.

Ken Wiscomb: As they currently have been.

Vyn Reese: And the problem is to make sure it doesn't take a week or so to do it. You know, that the problem so the guy doesn't end up in the hospital. That's my concern for these patients if it really could make a difference, which in probably some patients it could.

Patti Varley: This is Patti again and that's why when I read that statement I understand that, but that doesn't seem to be in that statement.

Duane Thurman: This is Duane. What you're saying is you are relying on the agencies to do their jobs in terms of how they make FDA approved drugs available.

Ken Wiscomb: This is Ken Wiscomb. Would you feel better, Patti, if we added like "at this time" after asthma?

Patti Varley: This is Patti again. I'm trying to find the words that would make it fit for me, but it's probably just me it sounds like.

Vyn Reese: So Jason, do you want to make that your motion?

Jason Iltz: Sure. So after considering the evidence of safety, efficacy and special populations for the treatment of asthma I move that we should not add the anti-IgE therapy drug class to the Washington Preferred Drug List for the treatment of asthma.

Vyn Reese: Is there a second or any further discussion?

Ken Wiscomb: I'll second.

Vyn Reese: All those in favor say, "Aye".

Group: Aye.

Vyn Reese: Opposed, same sign. That's passed.

Jason Iltz: Do we need to vote on your other four yet, Vyn?

Vyn Reese: We already did didn't we? Did we already vote on all those others?

Jason Iltz: I don't think so.

Vyn Reese: The one big one. Did we vote on that?

Woman: Yes.

Vyn Reese: Yeah, we did I thought. Okay. So moving along. The next scan is constipation drugs.

Megan Van Noord: All right. Are the slides ready?

Donna Sullivan: Not yet.

Megan Van Noord: Okay.

Donna Sullivan: Okay. Go ahead.

Megan Van Noord: Okay. So this is the drug class review on constipation drugs and it's the second scan report. The last report was completed in September of 2007 and included searches through April 2007. One previous preliminary scan is being conducted which was completed in August 2008. Next slide.

Included populations are adults and children with chronic constipation. Adults and children with chronic constipation associated with irritable bowel syndrome. Next slide.

The next two slides cover included interactions…or interventions. Sorry. There are seven different treatments listed under the five different classes being evaluated, which are 5-HT4 serotonin receptor agonist, bulking agents, chloride channel activator, osmotic laxatives and stool softeners.

Slide 6 lists effectiveness outcomes which are general subjective measures, specific GI symptoms, physiologist measures, general well being and/or quality of life, time to effectiveness, switching in patients not responding to a drug, and influence of treatment duration on effectiveness of drugs. Next slide.

Harms outcomes are listed on slide 7 and I can give you a moment to review those. Okay. Next slide.

To identify relevant citations we searched MEDLINE from April 2007 through August 24, 2009. We also searched FDA and Health Canada websites for identification of new drug indications and safety alerts. Next slide.

For the study selection one reviewer assessed abstracts of citations identified from literature searches for inclusion. Next slide.

Searches resulted in 80 new citations. Of those there were 14 new potentially relevant studies, which can be found in Appendix A of the scan update. Next slide.

So the new drug information is found on slide 11. Methylnaltrexone bromide was approved in April 2008 for the treatment of opioid-induced constipation. This indication does not meet the current eligibility criteria of our review. However, we mention it here because two POs notified us of this new drug. Under study for IBS-C is prucalopride, which is not FDA approved. Next slide.

Slide 12 lists new indications. Lubiprostone has FDA approval for the treatment of irritable bowel syndrome with constipation in women 18 years old or older. Next slide.

There have been changes to the lubiprostone label, which I can give you a moment to review because it's pretty lengthy. Did anyone have any questions?

Vyn Reese: Any questions from the committee? Take a motion to approve the scan.

Carol Cordy: This is Carol Cordy. I move to approve the scan.

Vyn Reese: Is there discussion or a second?

Deb Wiser: Deb Wiser, second.

Vyn Reese: All those in favor say, "Aye".

Group: Aye.

Vyn Reese: Opposed, same sign. It's approved. There are actually no stakeholders who wish to talk about constipation drugs. So we'll now turn our attention to the prior motion. There is one drug that wasn't on our list before. It is tegaserod. There's also a type-o. It should be polyethylene glycol 3350. It should all be on the same line and underneath that it should be lactulose, not [inaudible] whatever it is. It's lactulose. Yeah, that one should be above and then lactulose should be that l-a-c-t-u-l-o. Get rid of the Y. There you go. I think before we look at this drug class it was such a heterogynous group for all the different indications and that we just didn't feel like there was a way to add this as a class and they all had so many different mechanisms of action, different indications, subsets and different side effect profiles, which are becoming more worrisome that we just decided that we didn't want to…did not want to dive into that. Is there any other discussion about it? Does anybody have a different feeling at this time?

Jason Iltz: Well, from an access standpoint I mean there's some of these medications now, and most recently, the polyethylene glycol 3350 is MiraLax is available over-the-counter as is the docusate formulations as well and of course psyllium is there as well. So I don't know. Again, based on what we saw today there's really not a lot of evidence here that have been presented to…I mean, sure, they'll work. I'm just not sure where they fit from a PDL standpoint or if they fit.

Patti Varley: This is Patti Varley. For some of our patients who can't afford over-the-counter medications there are other drug classes where we write…they get prescriptions for it and I guess this hasn't come to my attention before as to if this drug class isn't on the PDL, if a patient is given a prescription for MiraLax, what happens?

Siri Childs: This is Siri speaking for Medicaid. We cover it.

Patti Varley: That's what I thought.

Vyn Reese: It just doesn't change.

Siri Childs: Right.

Vyn Reese: Actually, there's more evidence now that polyethylene glycol 3350 has been used for like six months. Some of these studies with no safety concerns which is…and it's an OTC drug now. So I'm not sure we have to do anything.

Duane Thurman: This is Duane Thurman. Just some background for the new members. We do not select alone the drug classes that we bring to you. And part of that is to, you know, so we're totally transparent. Those decisions are made by the governing group of DERP at OHSU and so the fact that we bring it to you does not imply one way or another what our position is on the appropriate placement of the drug class.

Vyn Reese: So any additional discussion?

Carol Cordy: This is Carol Cordy. I'm a little bit confused about the top three that are added in different from the motion from February 18th, 2009. And sort of where that fits in what we're…

Vyn Reese: They are just…they're new drugs some of them.

Carol Cordy: Except the first is taken off the market. Right?

Woman: Yeah. That was my comment.

Carol Cordy: So why is it up there?

Vyn Reese: It was removed from the market.

Woman: Yeah, Zelnorm was removed from the market in 2007.

Vyn Reese: Okay. Let's get it off there. They just still had it on their list.

Carol Cordy: Do we know anything about that second one, that combo drug?

Duane Thurman: I guess the issue is that it is sort of moot as to what drugs are included if it's not going to be part of…

Vyn Reese: It doesn't matter.

Duane Thurman: Well, they're only put together for our attempt to focus this as a particular drug class and…

Woman: Can't we just leave them all together?

Duane Thurman: We can do whatever you would like on those.

Vyn Reese: Since we're not going to add the drug class we can list them however you like.

Patti Varley: Yeah. This is Patti Varley. My just drugs for constipation should all be in one group and it should be one motion.

Vyn Reese: I think it's a small point. But is anybody going to make the motion? We're not going to add the class or this…anything in this treatment category then I don't think we even, you know, it doesn't matter how we list them. Does anybody want to reiterate this motion?

Patti Varley: This is Patti Varley. After considering the evidence of safety, efficacy and special populations for the treatment of constipation, I move that there is not enough evidence to make a decision to add this drug class to the Washington State Preferred Drug List.

Vyn Reese: Is there a second?

Christine Klingel: Christine Klingel, I second.

Vyn Reese: All those in favor say, "Aye."

Group: Aye.

Vyn Reese: Opposed, same sign. It's passed.

Jason Iltz: Just a quick point of clarification. There is one medication that they said didn't fit into this review. Does it help us to…would we say it's actually reviewed or did they say that…I mean they gave us some data under new drugs. The subcutaneous…so should we put that to the list or does it not matter? Was it officially not part of this review or was it part? I can't tell by what they had said. It said they did the meeting…the inclusion criteria.

Vyn Reese: For that review because it's only in a subset of patients that have opiates for terminal illnesses.

Jason Iltz: End of life, yeah.

Jeff Graham: This is Jeff Graham. I think that since it was brought forward by two states that said, "Well, this is a new drug," they had to say that. So they said it doesn't fit in.

Vyn Reese: Right. It's not in this category for general constipation.

Duane Thurman: This is Duane. Just to explain the frustration here we've talked about why are we even bringing these back to you when you have said that they're not on the preferred drug list once. And I think that I don't want to be in a position where the agencies are making that determination for you in the future. So I think that, you know, you can look at these drug classes. I think we are obligated to bring them before you and unless something seriously changes in the evidence I don't think that you need to spend a lot of time on them. But I do think we need to bring them to you even though you constantly tell us these are not going to be on the drug class. I don't think we can make the decision when we bring something to you. We'll bring you whatever OHSU produces.

Patti Varley: Right. And I…this is Patti Varley and I think it's good for the record to state that by not adding it to the PDL we're not saying people can't have them because I think that could be a misunderstanding. I think it's that they have access to them already. It doesn't need to be on the PDL.

Vyn Reese: Right. And there's so many OTCs here.

Jason Iltz: So how do we handle…this is Jason. How do we handle, for example, Relistor because that's going to be…you're going to get requests for it here and there. So whether Medicaid or Uniform Medical how do we…how do you guys handle that then? Does it just look like a medication that's never been considered and then you guys set your own prior authorization criteria or how does that work?

Donna Sullivan: This is Donna Sullivan. I'm not exactly sure what…how it's listed on our PDL but it would be…it would be subject to our normal plan design and

I'd have to actually look it up to…I don't think that we have any PA criteria on it that I'm aware of. Thad might be able to tell me.

Thad Mick: This is Thad Mick with ODS. We actually do have PA criteria for Relistor currently in place and I believe it's listed…I'm not sure where this hearing is for this point. There is PA criteria in place to ensure that it's made available for the appropriate population.

Duane Thurman: This is Duane. I just want to point out that anything that's not on the preferred drug list program is treated by the agencies as they always have treated the hundreds of other drug classes and I think for the new members it's also important to realize that when we talk about PA and all that that it means slightly different things from Medicaid. And that you're looking at different benefit structures in that they have plans, generally have a three-tiered plan where a co-pay is involved. That's very different than what Medicaid does and L&I has specific coverage criteria because it's a worker's comp program. So the big questions are probably what you want to hear from Siri. But I want to remind everybody that this is three agencies and that the PEP program has a substantial number of clients that are affected by this PDL.

Vyn Reese: Any other discussion? We already passed that motion. Let's move on to quick relief drugs for asthma. We need to hear the scan on that drug class. Is Susan Carson up?

Susan Carson: Yep, I'm on the line. Do you have the slides up?

Vyn Reese: We have our first slide up, yep.

Susan Carson: Okay. Thanks. This should be fast. There isn't a lot of new information. So this is the first scan for what would be the second update of the quick release medicines for asthma report.

Slide 2 just shows the history. The last complete update of the report was submitted in October 2008 and it had searches through May of 2008.

Next slide shows the included populations. We included adults and children with asthma including exercise-induced asthma. Next slide.

Slide 4 shows the included drugs for this review. There were five inhaled short-acting beta agonists included. Two of them are only available in Canada, but the three U.S. drugs are albuterol, levalbuterol and pirbuterol. And one short acting anticholinergic was included – ipratropium and we also included one [tape cuts out]; the combination of ipratropium and albuterol either in metered dose inhaler or nebulizer. Next slide, slide 5.

So our effectiveness outcomes included symptoms, health care utilization, change in treatment regimen for an exacerbation and mortality. The studies that only included pulmonary function test outcomes were excluded and then the harms outcomes were also shown on this slide—overall adverse events, withdrawals due to adverse events and serious adverse events. Next slide.

Slide 6 shows that we searched Medline for randomized controlled trials from the end date of the searches from the last report through September 2009 and although the searches yielded 73 citations after reviewing the abstracts and applying the inclusion criteria we found that none met inclusion criteria. So we have no new studies to report. Next slide.

Slide 7 we also searched the FDA and Health Canada websites for new drug indications and safety alerts for the included drugs and found no new information in these areas either. So really very limited new information for this drug class.

Vyn Reese: This is Dr. Reese. I had a question really quick. Terbutaline it says it's only available in Canada. Isn't it available in the U.S. too? It was on our list last time and I find it in my Palm Pilot.

Susan Carson: Well, that could be an error. If it is…it would definitely have not effected this…

Vyn Reese: Maybe it's an inhaled agent in Canada. Maybe that's it. Is terbutaline inhaled?

Susan Carson: That could be, yeah.

Vyn Reese: Maybe it's inhaled in Canada and just the oral is available here. That probably is it.

Susan Carson: Okay. Yeah, I don't…I'm sorry I don't know if that's the case but if we did find any studies of the drug we would have searched for them in this scan and found them.

Vyn Reese: Okay. Thank you. I'll take a motion to accept the scan.

Woman: So moved.

Vyn Reese: And a second?

Jason Iltz: This is Jason, second.

Vyn Reese: All those in favor say, "Aye".

Group: Aye.

Vyn Reese: Opposed, same sign. Any discussion? There's no stakeholders in this class.

Jason Iltz: This is Jason. Just a question – some time ago we had heard some data about potential overuse with this class and I know that we had looked at, you know, there were lots of stakeholders that said, "Well geeze, you know, really they shouldn't have more than so many fills per month and so many inhalers and what not" and I think we had decided at some point to ask, you know, are there going to be limits puts on how many inhalers you can get per month or how many inhaled doses you can get per month since they all contain different amounts. So where are we at with that process and where do we stand right now with how this class is regulated?

Sir Childs: This is Siri speaking for Medicaid and thank you Jason for bringing that up. We did bring you a package…a proposal to do a prescriber education in our April meeting last year and what we proposed to do and you all thought it was a great idea is that when we saw that they had exceeded a threshold, and I do believe that you said two inhalers per month, we would send a letter to the prescriber and that would be the extent of it. We would never put a stop on their albuterol inhaler. But I can tell you that you did a great job helping us with the verbiage for the letter going to the prescriber. Everything was all set, but we ran into some budget difficulties and had to really put that on the back burner and initiate eight DUR programs to try to reduce some expenditures in the Medicaid drug budget. So that has

been put on…it's ready to go but as soon as we can, you know, get some daylight then we do hope to do that. It's really worthwhile and I thank you for your help last year getting this all ready.

Patti Varley: This is Patti Varley. In lieu of the fact that budgets restrict that, my understanding is there are very specific asthma guidelines out there for clinicians to refer to. And that in that they talk about rescue medication versus maintenance medication. So we were really doing service on top of that, letting people know who might not have been attending to that detail as much.

Jason Iltz: This is Jason. I guess that I don't see really any reason why the previous motion would be one that would need modification and couldn't be just reiterated. So I guess that's the motion I would make that we reiterate the previous motions dated February 18th, 2009 and bring them current to today; and there were two of them. One for the combination and then one for the other group as well.

Vyn Reese: Any discussion?

Ken Wiscomb: This is Ken Wiscomb, I'll second.

Vyn Reese: All those in favor say, "Aye".

Group: Aye.

Vyn Reese: Opposed, same sign. It's passed. We're adjourned for lunch. Be here at 1:00.

I'd like to ask people to take their seats now. We will reconvene the meeting as the Washington State Drug Utilization Review Committee. The first item of business is looking at our minutes from the last meeting, from December 16th. Are there any additions or corrections to those minutes? This is Dr. Reese. I have one. My name is misspelled in the first paragraph. It's R-e-e-s-e.

Jason Iltz: This is Jason. I have a couple. On page 10 the unidentified male is, I believe, myself. I think I've been identified since that time and then on page 26 I believe it is, page 26 towards the bottom, second to last sentence

the…where it says, "It's written substation permit" it should be substitution permitted.

Vyn Reese: Any other additions or corrections? If not, I'll take a motion to approve the minutes as amended.

Jason Iltz: So moved. This is Jason.

Vyn Reese: Like a second please.

Susan Rowe: I'll second. This is Susan.

Vyn Reese: All those in favor say, "Aye".

Group: Aye.

Vyn Reese: Opposed, same sign. The minutes are approved. The first item on the agenda today is going to be talking about the Narcotic Review Project Plus program. Go ahead.

Siri Childs: This is Siri Childs again speaking for Medicaid and I would like to introduce first of all Dr. David Tauben who is our UW pain specialist that is our consultant on this program. David, would you like to say a few words?

David Tauben: First, thank you for inviting me and I just wanted to stress to the committee and everyone else in attendance here that this is viewed as a very, very high priority issue to the state as the University of Washington is standing by in commitment to help educate the providers, identify problems in patients early and at high dose opiates and develop alternative treatment plans that we can institute. We are doing a chart review and then a direct contact with the provider to discuss issues which allows a two-way conversation about care and at this point we just roll this out and so far we are in 100% agreement by the providers that are recommendations are appropriate and are acceptable, which should have a very significant impact. At this point it does not feel at all adversarial and indeed appears to be educational, instructive and much appreciated by the first pass providers. I understand that we're selecting out, at this point, the highest opiate dose prescriptions in the entire program. So these are the most difficult of all and at this point, so far, we've only had a handful that

we've started up on. We've had very good success. So I'm happy to be available as a resource here and look forward to the rest of the conversation that you all are apparently about to have.

Vyn Reese: Thanks Dr. Tauben.

Siri Childs: I would like to introduce Karen Wilson who is one of our case managers…nurse case managers and then she'll introduce the entire team. And I just want to put in a little plug for our nurse managers because as you know probably in the last two years we've brought our narcotic review program to you several times and every single time we've laid out the problem and we've, you know, tried to think of solutions on how to address this and I can honestly say that having nurse case managers is the ticket. We can now marry up our claims with our nurse case managers and finally get something done. So without anymore I'd like to introduce Karen Wilson who will introduce the rest of the team.

Karen Wilson: All right. Thank you Siri. I'm Karen. I'd like to introduce the rest of our Narcotic Review Program Plus team – Lana Griffin to my left in the red sweater is the other nurse case manager. You know Siri of course. Chuck Agte, Amy Irwin directly to my left and on the end is Scott Best who is one of our nurses with the patient review and coordination program. I just want to tell you I'm suffering from a bit of a cold today and I'm very hopeful that no adverse events will happen while I'm…sneezing fits and that kind of thing. So I'll apologize in…before all that.

We understand that you've heard a lot about our narcotic review program and we're here today to share a little of our early experience and we think success. Having said that it is early and we're just about two weeks shy of having our first six months into this program. So it is very early yet. Lana and I will go through our slides with you and as you have questions we hope that our team can help provide the answers. Next slide please.

So we wanted to…just because we know that you've heard a lot about Narcotic Review Program we aren't going to go into the weeds of the details about that. But just to briefly go over a few things, the goal of the Narcotic Review Program is to work with prescribers to reduce misuse of opioids and improve the quality of life for our Medicaid recipients. Next slide please.

In terms of a principle some kind of key things about our Narcotic Review Program; I won't read the entire slide. It's got a lot of words on it, but we do routinely send pharmacy utilization reports to prescribers as well as ER visit reports and inpatient hospital reports, etc. when indicated. And I don't think we have the data on it, but that was one thing about this first initial six months. I personally have been a little surprised that we didn't see more higher utilizers of service. I thought many of our people that we looked at in the Narcotic Review Program would maybe have just barely missed some of the criteria to be included into our patient review and coordination program that sort of…that finds high utilizers, over utilizers of emergency rooms, multiple pharmacies, multiple prescribers and that kind of thing. And by enlarge that's not the case. These are folks in this high, high dose range that aren't going to the emergency room for narcotics. They just are hooked into one prescriber with huge massive doses in many cases. So it's very interesting, very, very interesting.

As Dr. Tauben said and I said too, our goal is to work collaboratively with prescribers. Opioids are not stopped and we do not enforce taper plans unless the prescriber and HRSA are in agreement and/or the University of Washington Medicine Center for Pain Relief review is done and there are some recommendations given and I think Dr. Tauben spoke about that. It's a real strength of our program and a real sell, I think to some of the prescribers that have had such a hard time quite frankly with some of the clients. Some of these folks are not easy people to take care of and to have in your office with their demands sometimes, to be quite honest about.

In terms of where we head when we have someone on a taper plan; as a reminder the agency medical director's guidelines refer to around 120 MEDs per day as the high end of a medically necessary opioid dose. So when we make the decision to taper a client's opioids the lowest effective dose or zero is done a case-by-case medical necessity review in consultation with the prescriber and/or the University of Washington specialist in those cases that are reviewed by a specialist. Next slide please.

In terms of overview and I think it's important and as Lana and I do our work and we're interacting with prescribers and others sometimes people in the office I think the educative aspect of this can't be overstated and the reason why we're doing this program; I know I personally have learned a

great deal since entering into this work. I don't think…well, I think it's important to stress the significance of the problem in our state. Washington is one of six states in which opioid prescription-related deaths not outnumber traffic fatalities. We share that dubious distinction with Connecticut, Massachusetts, New Jersey, Ohio and Rhode Island. In 2006 and 2007 Washington's rate of self-reported non-medical use of prescription opioids was the fourth highest in the entire nation. And then as you know Washington is in the top 10 states for opioid prescription-related overdose or poisoning deaths and over half of those deaths are in the Medicaid population and this is just not okay in our state. And I think the more we go back to those kinds of things when we're working with people I think the better off we are. I think many people know about this but not everyone does. On a personal note I think that it took us a while to get to this place and it will take us a while to get out of it. But we need to start somewhere that's for sure.

Dr. Alex Kahana that's with Dr. Tauben at the University of Washington Medicine Center for Pain Relief calls this a public health emergency in our state. And that certainly should call us to action. Some of the details of the programs – we started the program September 1st with 100 clients all over 100 MEDs a day and there was a variation in that. Some were just over 1,000, some were over 5,000. I think we had somebody over 6,000 too. So some variation, but all very high dose. We excluded people with cancer, clients that were in our Hospice program, in nursing homes or were dual eligible meaning they had Medicare and Medicaid, because we're not the controller when someone has Medicare and Medicaid. We did notify clients and prescribers of the start of the program – clients were sent a letter about NRP in August of this year and Dr. Thompson notified the top 85 opioid prescribers in the state Medicaid program also by letter in July. Next slide please.

As Siri mentioned the Narcotic Review Program Plus is the first time that HRSA has combined claims data with clinical case management. We use a multi-disciplinary approach with our internal clinical team that includes a pharmacist, a medical consultant, RNs, pharmacy program staff as well as representatives of behavioral health and chemical dependency fields within HRSA. So our approach is much broader than simply reviewing each and every prescription. We're really trying to tie together the entire person, as well as the health care team that surrounds that person and that

we know that that includes physical health, behavioral and chemical dependency.

All opioid prescriptions require prior authorization for clients in NRP Plus. HRSA sends the prescriber a short form to complete and return to us on each and every opioid prescription an NRP clients presents. Then the nurse case managers get involved with the case focusing in on the medical necessity for such high doses of opioids. We talk with the prescriber, get medical records for review and work with our multi-disciplinary clinical team to get input and make decisions on how to proceed if the prescriber wishes to taper the client's opioids and/or review by the University of Washington Medicine Center for Pain Relief is requested or needed.

We encourage prescribers to tape opioids per the University of Washington guidelines and our hope is not just to impact an individual case, but actually to influence the prescriber's prescribing behavior and patterns over his or her whole panel. Next slide please.

Lana Griffin: Next we'll talk about some enrollment statistics. So in September we started out with 100 clients on this program and since then we've had to remove nine clients because three of them had other primary insurance. One was placed in Hospice, one was placed in a skilled nursing facility, two had compounded prescriptions, one had a cancer diagnosis and one was enrolled in Medicare and we found all of these things out during our review of the cases as they came out. So now we have 101 clients because we've added 10 clients. So currently we actually have 17 clients that are on taper plans and actually I need to correct that because when we started the slides we had 17. We now have added one. So we have 18, possibly 19. There's one that I'm working with a physician. I'll be bringing that to our team next Wednesday. So hopefully we'll get that approved.

Six of our prescribers have multiple clients on the program. There's actually one who has, I believe, five or six in the program and there are 82 prescribers that have clients in the NRP program. So that means that 82 letters went out in July notifying these prescribers that their clients were in the program. Next slide please.

So now we're going to look at the average morphine equianalgesic dosage per day for our clients. I want you to look at the different colors on the screen there. So the blue represents those that were targeted for the

program. Those are the 100 clients. When we started this there were…we looked at people that were over 1,000 morphine equianalgesic dosage. We started with 300 and then we put the top 100 of those 300 in the NRP program. So the blue represents those that are in the NRP program. The red represents those other 200 or so that were targeted and the green represents the sentinel effect. Those were the rest of the opioid using clients that were…of the 82 prescribers, excuse me. And so you'll see there that when the letter went out in August you'll see there's a huge dip in the MEDs per day of those in the program. It seems that, you know, when we let the prescribers know that this program was going to be in effect that it had a huge impact on that because there was an immediate dip in the MEDs per day for those clients. We started out at around 2,100 per day for these clients and now we're just under 1,000. So I think that's a significant change. Next slide please.

Next we're going to talk about the average units and when I'm talking about units I'll just say tablets or capsules. So again we see that our NRP clients theirs was right about 1,000 tablets a day. And if you see now that they are just over maybe 500, 550. So that's almost half there. You'll see also the ones that were…that are not in the NRP program, but those that were targeted also have a decline there. And also you see that in the green that there is a sentinel effect going on. So I think there's some outreach going on with the prescribers that actually have those people in the NRP program. So that's also a very good thing I think. Next slide please.

Next we're going to look at the average cost. This is dollars per month. Again, you'll see those in the program; there's a significant decrease in the cost per month for these clients and also there's…so we went from what almost 550 per month to a little over 200. Again, about half. There's also that decrease in those who were targeted but not in the program and again we do have that sentinel effect going on down there in the green.

Patti Varley: Can I ask what the peak we think is from in July?

Lana Griffin: Where? Let me see. For the…

Patti Varley: If you look at the blue line there's a huge peak in July.

Man: Right. Well, that was showing that these clients were getting an increased cost every single month right up until July. The very next point on this is

in the time period when they were actually in the program and so that's why it drops after that. There's no reason to believe that it wouldn't have continued to climb if we hadn't done something.

Woman: Is there any reason to believe that the actual medicines that those people were receiving were not being ingested?

Man: In other words were they selling them?

Woman: Diversion.

Lana Griffin: There is that…there is that possibility of diversion there. We have a couple of cases where it's highly suspected…it's very, very difficult to prove something like that. That's really all I can say about that.

Patti Varley; This is Patti Varley. The cynic in me, when I looked at that peak, I was curious as to whether there was knowledge that this was coming down the pike and that people got…I'm just curious what…you guys are in that. But that's a…even though it's going up and it had been going up that's a huge increase right there statistically and it's right before this goes into effect. So I'm just curious if in your investigation so far and your work so far you've seen any sort of theory or conclusion as to why that was. Were people getting a bunch of prescriptions knowing that there was going to be this review?

Chuck Agte: In looking at the claims data there is some indication that…this is Chuck Agte for the record. There is some indication that may have been going. It's hard to pin it down that way because in the month where you see the spike the patient's had not yet received their letter, but their prescribers had received a letter saying that they had patients who would be enrolled. So it's hard to say if it's chance or if it was purposely knowing these clients because at that point where you see the peak the prescribers would be the ones who had the direct information and its…I can't really conjecture why they might have helped in the process at that point. But that would be what you're looking at there is prescriber knowledge of the program and if they were sharing knowledge of the program with their clients before we had gotten the letter out to them.

Siri Childs: This is Siri and when I look at data like that I tend to look at the slope of the line and the trend and I believe that Scott Best is probably right in

saying that who knows where this would have gone because the slope of the line is definitely increasing.

Ken Wiscomb: This is Ken Wiscomb. Were there any providers that were there before the increase that weren't there afterwards? I mean was there any disciplinary actions that might have eliminated some over prescribers?

Siri Childs: No. I do want to mention, you know, looking at this particular chart, this is cost. And I can tell you that along about that time generic OxyContin was taken off the market. And so a lot of that could be OxyContin brand that we're seeing too.

Patti Varley: Aw, that makes sense.

Carol Cordy: This is Carol Cordy. This we opened it up to questions you'll never get back to your slides, but I had a question. On your numbers it sounds like about 20% of these 100 are on taper program. I was just curious why the other 80%...I mean why that's so low really. Because these are huge doses.

Karen Wilson: Yeah, it is. And it's just a function of how fast we can get to the cases to work with the prescribers on them.

Carol Cordy: Okay. So it's not…

Karen Wilson: Two RNs, you know, with 100 cases. Yeah.

Carol Cordy: Okay. So it's not that they didn't…

Karen Wilson: No. It's not that the others have said no. It's that maybe their prescribers have been slower in responding to our request for paperwork.

Lana Griffin: It's also not that we haven't talked with them about a taper plan. Some providers out there really think that it's medically justified for them to be on these high dosage. So again then we talk about maybe having them have a second opinion by the UW to really look at that because I do believe that a lot of prescribers really think that, you know, when their patients come in and say, "This really, really, really hurts," you know, pain is so subjective that they go ahead and prescribe. So for those who have been a little bit easier to get on a taper plan I think it's maybe in the

back of their mind they maybe suspected that, you know, that dosage really wasn't as effective for them as the patient said it was. So I think that's why; maybe a reason.

Carol Cordy: So do you have that other number of how many have been approached and said no?

Lana Griffin: Almost all of them have been approached but it's not necessarily that they've said no. It's the process of us going back and forth and asking for the medical necessity piece, let's see your documentation, which to show us that it's medically necessary for them to be on this high dosage of medication. There's the communication back and forth which takes a lot of time.

Carol Cordy: Okay, thank you.

Karen Wilson: Yes, very much so.

Patti Varley: You can tell me if you don't want more questions now, but there's two things that I thought about. One is being a nurse and a nurse practitioner. This actually came up in a nurse practitioner group and one of their issues was about access to that second opinion both in regard to time and cost to the client. So I just didn't know if, you know, if you've got people who need that what…do we have a sense of that as far as who incurs the cost and what the timeframe would be for that second…

Karen Wilson: There's no cost to a Medicaid recipient for a covered medical services and we even pay for transportation; the state Medicaid program does. And those are something that, you know, the University of Washington is used to arranging transportation for Medicaid clients in all of its many clinics I do think. In terms of the time, yeah, we're still working on that—how long it takes to get reviewed, but it's a work in progress. We're six months into it and, you know, that's as far as we are. I think it's wonderful to have the University of Washington. As a center for excellence it is such a plus of our program, it is such a good thing to have with our prescribers.

David Tauben: Actually my preliminary expectations that at this point over a minority of those prescribers are going to actually require the patient to be seen at this point.

Carol Cordy: So will you do some consultation over the phone?

David Tauben: First it's a record review and then it's a conversation with the provider. The record review apparently is laborious because these records have to be accumulated and the staff is spending a lot of time providing a working set of documents for me to go over. We do have a bit of a bottleneck because I'm the…at this point the only reviewer and we're trying to introduce that and determine the horsepower needs in terms of providers at the University right now being a pilot program. There is a little bit of a backlog, but I think it's going to be unusual for a provider, after the review and a conversation…at this point I spend up to an hour going through the case with each provider. We schedule a time. We don't interrupt them in the middle of their day. They don't interrupt me in the middle of the day. So it's reason time with calm voices and a very reliable and accurate record review and discussion. So that's going to minimize the increased expense of actually having the patients be seen in consultation.

Patti Varley: And the other thing which is a total aside was the either rumor or reality that there was a major pain clinic that existed that has been closed. Does anybody know anything about that?

Woman: Is that the one in Vancouver?

Patti Varley: I actually don't know exactly where…just in the middle of this discussion with my group there was talk about that.

David Tauben: There was a number of providers and they've lost the schedule two licensing, but the clinic is still open.

Patti Varley: But they can no longer…because I didn't know if that affected numbers or not.

David Tauben: Well the absence of providers distributed that population into the greater Vancouver area and created a crisis of great concern because there was no place for these folks to be handled. So that may be reflected in the overall numbers.

Patti Varley: I'm just curious.

Karen Wilson: In terms of what we hear I can tell you what we hear from prescribers about why clients should be on these high doses; that's one of the reasons, i.e. I inherited this client from someone else, is given as kind of a reason and I can understand that. I mean that is a problem, but that's not a medically necessary reason to keep someone there. But it's something that we all need to understand. Another thing we hear from prescribers is that patient has been stable on this dose for years. And that again is something when you kind of step back, okay let's try to understand this. This has been going on for a while. It's hard to get an inroad in but yet we kind of have to do that. But those are two of the things—I inherited this from so and so or from someone else and that can cluster in communities as the discussion was it unleashed in Vancouver all these folks into the other, you know, and if some prescriber is wonderful enough to accept three of those patients because we know they need doctors and nurse practitioners too, then that prescriber really has a…compounds his or her own problem. So it's an interesting and difficult issue I think.

Lana Griffin: Okay. So can we go to the next slide, the nurse case management slide, please? So I think the nurse case management that's the reason why Karen and I are here to sort of explain what we do and I think it has had a great impact on this program. I think those have really helped our numbers to go down. So when we contact the provider we do it via phone, fax, or secure email. I've spent many hours on the phone. I've spent many hours faxing and I've spent hours doing the secure email, for sure. So when we first become involved with the case, you know, we generally talk to the prescriber after we look at the claims data, after we look at the authorizations and we see what exactly…what the patient's diagnosis are, what their ER visits have looked like, if they've…what other prescriptions they're on. So we're looking at all of the claims and we ask for chart notes for the justification for those high opioids that they're on. A lot of times we'll see that sometimes there are multiple prescribers involved and that's when we get on the phone and talk with the provider and say, you know, I see this and this and this is happening. Do you know that they are seeing this prescriber and this prescriber? Did you know that? Even though, you know, when we send out the authorization form to be signed we give them a drug profile and it will show different prescribers on there, but sometimes they sign it anyway. I don't know if they actually know that this person has actually been doctor shopping and has seen maybe two doctors in two weeks, you know, and getting opioids for each of those visits.

Sometimes there's the issue of, you know, people having benzodiazepines on board. Any sort of medication reaction we talk about that. A lot of times it's about us talking about the program and why we're here and we talk about the health and safety of our clients. And I think if we put that first and foremost when we talk to our prescribers I think maybe it eases them a little bit because we're not there to attack, we're not calling them and saying, "You're a bad prescriber. You don't know what you're doing." That's not what we're doing. We cannot do that. As a nurse I can't tell a prescriber that you're awful. I'm not going to do that. I'm telling them, "I'm worrying about the health and safety of our client". And so I think when we come with that approach it works best.

Ken Wiscomb: Do you have best practices plans that you suggest or…like pain contracts and…

Lana Griffin: Oh yes, we do talk about that. We ask for all of those things when we ask for our documentation. Most of the time they actually have pain contracts already.

Ken Wiscomb: If they don't have that do you have templates that you recommend and give to them?

Lana Griffin: Yes, we do.

Ken Wiscomb: Oh good.

Lana Griffin: Next slide, please.

Siri Childs: Lana, could I just expand on that a minute? This is Siri and please keep in mind that the foundation for all the work that we are doing is the agency medical director's guidelines. And so all of that information, everything that we are saying can be found in those guidelines.

Lana Griffin: Yes, I did forget to talk about that piece. When I call up a provider and I say, "So and so is on this medication. I'm sure you're aware of it. Do you know that according to the agency medical guidelines dosage calculator this equals 4,000 MEDs and the guidelines say that maybe they shouldn't be more than…it's rare that someone is more than 120 a day." And it's usually, "Oh, really?" So I direct them to the site. I do that over and over

and over again. I direct them to the site. I show them where the calculator is because it really is about re-educating the provider.

So let's talk about some success stories. This one is mine. I have two. Client A she's a 37-year-old female. She had a diagnosis of rheumatoid arthritis. As you can see she was on methadone and oxycodone. Her MED, morphine equianalgesic dosage was over 1,000. When I looked at her claims data the first thing I saw was that she was on a ton of opioids every single month. She never missed a month, however there was no medication for her rheumatoid arthritis. So I called the doctor with my findings and I said…actually I asked for chart notes and in the chart notes it showed that the doctor was trying to do the right thing. He actually had her go to a rheumatologist and in that chart notes the rheumatologist aid, "Patient is taking methotrexate". There was nowhere in claims data that she was taking methotrexate. When I called the provider and talked with him about my findings he was very surprised. He had no idea. He thought she was getting it and taking it. He said he would talk with her about it and when I received a call back from him he had put her on a taper plan because she was in fact not taking the methotrexate. She was just taking all of her opioids. So the outcome was that he actually did put that patient on a taper plan and she actually…the latest claims data shows that she's at least getting her methotrexate. So that's good. Next slide please.

Then we have client B. She is a 36-year-old female with degenerative disk disease of the lumbar spine and fibromyalgia. She took methadone and hydrocodone/APAP. She had an MED of over 1,000. In talking with the provider I talked with him and we talked about her going to a pain specialist for other interventions for her back. He said he had tried everything. So the end story is that she did end up getting spine injections and she actually reports improvement with her legs since those injections. Her outcome is that she now has a MED of 320. So she has a significant improvement. Next slide please.

Karen Wilson: This is client C. This was one of the first cases I worked on back in September and client C is a 61-year-old female with a diagnosis of rheumatoid arthritis and recent stroke. We looked at her utilization data and looked at some progress notes. By all accounts this woman was very, very debilitated—bed bound and dependent on her DSHS paid care givers who were family members. Actually, the client's own mother and the

client's own son for all of her care including, of course medication management. And over time there was, as I discussed her case with other people, it was clear there was a concern among those involved with her care about the large doses of opioids in the home and the caregiver situation. The home situation was very, very fragile. It was difficult at times because they couldn't find a skilled nursing facility that would take her because of all the opioids that were involved with her. They had actual fear. So it was an interesting case. Aging and Disability Services Administration is the part of DSHS that oversees Medicaid paid caregivers in the home. We worked with ADSA staff who performed a home safety assessment and I always felt really good to have been a part of this case and I always feel too that it was kind of a confluence of events that happened. I think there was ongoing, you know, there had been concern. The client status had recently changed. She had the stroke in the early summer, I believe. But the caregivers were terminated and the client…they found a SNF that would take her and it's a good SNF too. I used to be a head nurse in a nursing home. So I know a thing or two I like to think and I've talked to those folks. But I felt that for this client it was such an important intervention in her life to get her out of that home and out of that situation. There were indeed adult protective services referrals filed in this case. There was some incidents of verbal abuse with the caregivers in addition to the concern about diversion and that.

And when we look at her actual use of medication or what we paid for anyway, we'll never know what her actual use was, in July of 2009 we paid for over 5,500 MEDs per day. When we look in December when she's in the skilled nursing facility look at that, 133 MEDs per day. Such a dramatic decrease in actual morphine and OxyContin use. That was a very dramatic case and I really felt that our program was very helpful in this case. Next slide please.

Client D is more or less I think a success story in progress. Certainly not as dramatic, but interesting none the less. Client D is a 53-year-old female with a diagnosis of HIV positive, episodic abdominal pain and degenerative lower back disease. We did our usual look at utilization data and progress notes from the prescriber who was her primary care provider. This client actually, Dr. Tauben reviewed her case and actually saw her face-to-face quite recently and in August of 2009 client D was on 2,500 just over MEDs per day and now she's down to 1,680 MEDs per day. Still a very, very high dose. I realize that's still very high, but we're

making improvement. We're making improvement and she's completely off her short-acting opioid which is wonderful. Her methadone dose is lowered and what's maybe most important is that this gal is on board now. She saw Dr. Tauben, she thought it was wonderful. I think she came to that conclusion perhaps after she'd had a couple days to think about it, if I remember correctly, but bless her heart. It's a good thing. It's a good thing. Next slide please.

Lana Griffin: So next we'll talk about some provider impact and success. The first provider I'm going to talk about he is a physician in Northeast Washington. He actually inherited a good amount of pain patients. He also has the most clients in our NRP program. He's the one I believe with five or six. In the first beginning of this process, you know, a couple of days after…in the beginning of September we would send requests for authorization to this provider's office and every single one of them, not every single one, but a lot of them came back saying, "I already signed this. This is the same auth. I've sent this fax three times." And so I called the physician and I explained to him exactly what the auth process was. I told him that every single time you write a prescription for this patient or any patient that's in the NRP program there has to be an authorization for it. You have to sign the authorization for it. So he didn't realize that when he saw the patient once a week, and every single week he wrote a prescription for them he's going to get one once a week. And so once we figured that out he was very happy to go ahead and go ahead with the authorization process in the way it's supposed to be and actually it turns out that he's really happy with the program, he's the one that has I think almost all of his clients on a taper plan with us and he's no longer resistant at all. He thinks that it's a great program. He said to me that after a certain…after his patients hit a certain MED once they got lower and lower that they reported that there was sort of a fog that lifted for them and he's actually very, very happy with our program. So I'm pleased to discuss that with you guys. Next slide please.

Karen Wilson: And provider B is a physician in Eastern Washington. The diagnosis of her client is untreated rheumatoid arthritis and when we looked at her progress notes month after month there was written in the notes, "Client unable to find a rheumatologist to see her" and then that was the rationale for the high doses of opioids was the fact that, again, she wasn't getting her rheumatoid arthritis taken care of.

So when I looked through her utilization data what really was alarming to me…and there's a little type-o on the slides in your book. The slide up there is correct. Her dose of methadone had just escalated in a calendar year. It was really alarming. In October of 2008 she was taking 1,920 MEDs and a year later she was up to 3,360. That's just alarming. So I sent that over to the doctor, that big long report with her doses of methadone underlined so she could see it. I think it's one thing as a doctor when you're a busy, busy doctor it's one thing to look back through chart notes. It's another thing to look at a concise report and see what's going on. You know what I mean? It kind of opens your eyes I think. And I think it really did catch her attention. I spoke with her on the phone and she's told me that she was really uncomfortable with that high dose and was really surprised at how much it had escalated. And you know when I hung up the phone I remember thinking to myself, you know, if I lived in that city I might go see that doctor as my own doctor. I mean she wasn't a bad doctor. There was nothing in the conversation that led me to think she was a bad doctor. This just got away from her and I think it's true of a lot of prescribers and thus we kind of come back to the unlearn and reeducate kind of mode.

We talked about it and either there aren't any rheumatologists to see this woman where she is or she's unwilling or unable to find one. So the doctor's office was working a little bit more stridently with her to find a rheumatologist. Last I spoke with them I think we had come to the conclusion that she would need to go to the UW Rheumatology Clinic and they were making arrangements to do that and we're working on tapering her short-acting opioid at the time. So that's a good thing.

So that's the end of our slides and if you have more questions we're happy to try to answer them.

Carol Cordy: This is Carol Cordy. I have a question. It seems like these patients seem pretty legitimate, but I imagine there's a lot of people who are diverting.

Karen Wilson: Yes, I think so. That's my personal opinion.

Carol Cordy: And besides doing a talk screen, which may show the methadone or the oxycodone how…do you have suggestions of how you figure that out? I mean I think some people are supporting themselves on selling the prescription drugs.

Chuck Agte: One thing that we have found in analyzing the claim data after the beginning of our program because there is…has been that dramatic drop in the morphine equivalent dose and as we started to look at the claims data for these individual clients. Along the lines of what you're questioning about we have found that in any of these 100 patients in any given month since we started the program you can see every single one of these clients filling narcotics like clockwork every single month since they got the letter and the program started and their narcotics require PA and it's not even consistently the same group of clients. In any given month 30 of these patients don't get any narcotics at all. So that's an indication that there possibly has been diversion and/or stockpiling going on. We have seen that in some cases where it appears less a diversion issue and more people are stockpiling their medications, but the utilization pattern that you see is that, and again it's not like there's a specific 30 patients, it's in any given month about 30 of the patients don't get any narcotics that particular month.

Patti Varley: This is Patti Varley. I also want to mention that I work with children and adolescents and some of the refills that their parents are getting for their pain meds are due to the fact that their pills are disappearing and the reason they're disappearing is because the kids are actually either using, selling, partying with them as well. So to me I have another level of concern, which is the access out there of these bottles just being randomly available for access to our children, which is just an aside point to the great work you guys are doing is limiting that access.

David Tauben: David Tauben here. I just want to respond that the AMDG guidelines recognizes and you practitioners involved in this the problem of diversion and a yearend drug screen that is negative, particularly for methadone which is 4 to 10-day half life so it's very difficult to say I forgot the pill this morning before I came in the office. We consider that a breach of contract and an indication for either a referral of treatment evaluation or a rapid detoxification based on non-compliance with treatment. We call that arrant behavior is our terminology in the Pain Center at the University of Washington and the AMDG guidelines are also making the new version, which will be due out hopefully by the end of April and make a much more concerted effort to describe how urine toxicology needs to be interpreted, protocols for ordering, frequency, expected costs, onsite versus send away referent the costs and access. So at this point you're

absolutely right that the only way to evaluate is by urine screens, but a urine drug screen that's negative on a patient on methadone cannot be accounted for.

Carol Cordy: I think the trouble is it can be positive, but they're not taking their 100 pills a day. They are selling half of them.

David Tauben: One of the observation I just wanted to comment that having been involved in the opioid dosing issue for most of my career and involved in the regional department of health freeing up of the amount of opioids available back in the mid 90s it's quite clear that it is a rare patient that needs the kind of doses that many of us practitioners just relearn and reeducate. I would say that applies to me as well as an expert. I relearned and reeducated myself and this relearning and reeducation is being very strongly promulgated amongst the primary care community in particular at all aspects—both physician, nurse practitioners, DO and the like to recognize that it is an unusual circumstance for doses that high or offering any significant advantage and the view is that once the sea of opioids, the faucet is turned off in general, the diversion and the death rate amongst teens who are going to, you know, you described bowling parties where they reach into the bowl of drugs.

Interestingly I was at the University of Wisconsin last weekend on Grand Rounds and spoke about that at dinner with a couple I was being hosted by and on the TV news was an 11-year-old who died of an OxyContin overdose. I mean just followed my conversation. They said, "What's this about a kid dying of OxyContin." It was right out of the script. So this is not just statewide. This is a national problem and I want to compliment the State of Washington here taking the leadership because this is going to be viewed as a landmark activity that the State of Washington is doing and that will spread across the country. You heard about the number of states earlier on. It is a very big problem and diversion is a very big problem, and diversion is a very significant issue that the practitioner has only a small role in.

One of the other projects that is a statewide initiative that the University is participating in is a teen drug abuse program to identify strategies. It's going to include education of how to dispose unnecessary, unused opioids to recommend to providers to give to or for hydrocodone after a root canal for instance instead of 50 to reduce the surplus of drugs and to just spread

by word of education to providers that any extra pills are going to likely get the community at large, including their own children, into significant trouble. So it's a very complex problem that extends beyond HRSA, but will have a significant statewide effect through what's been identified as the sentinel comments.

Carol Cordy: I have another question about the TOX screens. What are you doing? Is there a standard for what to do with all the other stuff that shows up on the TOX screen?

David Tauben: Well, if it doesn't belong there it's aberrant and aberrant is considered…aberrant behavior means losing a prescription early refill, stolen prescription without a police report and the like. And if there is an aberrant drug it may or may not be valid. A benzodiazepine they forgot to mention that their psychiatrist may have offered it or what have you, but we consider for instance cocaine to be a guaranteed diversion because the opioids have been sold for transition to cocaine and there's no false/positive for cocaine and it's a very selective test. Positive opioids of other kinds are not automatic disqualifies from receiving prescriptions but it generates a very significant important conversation, increased degree of surveillance and the inclusion of additional consultative support.

This is actually spelled out…it will be spelled out in the new AMDG report that will be available within a couple of months. We spent hours on hammering out exactly the questions that everyone here has. How do we communicate the facts of this prescribing problem? But there is a specific recommendation as to frequency of urine drug testing, significance of testing, what you have to ask for. For instance the typical drug screen – the [inaudible] of five doesn't even include oxycodone, which seems to me a big problem since that's one of the drugs of most predominant abuse. So it's clarified for the provider, for the primary care doc, in the remote community what to do and how to interpret the test, an algorithm has been drawn out and has been approved by all the experts who are involved in the formulation. If your patient is suspicious you get the positive, if the positive is…you get a gran…you've got a GS confirmation and really a step-by-step, easy-to-use algorithm is going to be included within the actual guidelines.

Carol Cordy: And where is that going to be?

David Tauben: That's going to be on the AMDG website once it passes final muster, the Agency Medical Director's Group and we are hoping to have this finalized by the end of April. So certainly by the summer very detailed with links to opiate risk tools to psychological screening tools. All free and many of them included in the guidelines. It is very easy access to provide this educational tool. There's also an effort made to increase the number of consultants that will be available. So it won't just fall and to increase the variety of consultants, phone call, exchange of just medical records, teleconferencing and the likes. So patients in rural areas who would find it very difficult to get to an urban area where there are consultants and also to train. We're looking at champions within clinics statewide or in regions who identify themselves as interested in becoming more expert and we're developing a training program where they can for instance send their patients to our clinic the same day they're there and we evaluate them with the actual primary care doctor, kind of look over the experts shoulder so to speak, see their patients, see other patients and half day mentoring. It's really not that hard to do to fix up a big problem. And so I consider it fairly low hanging fruit, but if we can find providers in rural areas who are interested in signing up, and they will be paid. There's a pay structure. Worker's comp has agreed to pay. Most insurers offer a code for providers so that they're not doing purely pro bono. That they can actually be compensated for their work. So we're expecting a rise in specialists, increased educational tools at hand, guidance for how to handle these problems and further justification of these numbers that we set.

There's a publication just in January, Annals of Internal Medicine from the Seattle group, Dr. Van Korph at Group Health and several of us at the University of Washington, I think it was the January 12th Annals of Internal Medicine that identified a 9.5 fold increase in death in doses above 100 MEDs compared to 20 mg of less and there's a fairly straight upward curve, again, supporting the risks associated. And I would say a paucity of evidence both on the clinical side and literature that doses much above 120 MEDs really provide the patient any additional advantage. Basically when you have all those new receptors jammed up there's nowhere else to go except into toxicity. So there is a ceiling effect that we didn't appreciate as recently as 15 years ago.

Carol Cordy: Thank you.

Vyn Reese: What about ensuring that your patient's urine TOX screen is actually there. Is there any mechanism you use to do that?

David Tauben: Any mechanism…if you go on the internet and look how to scam the doctor. They're actually X rated scams. So you could even witness the urination and still be fooled. So we've considered that a police and detective action rather than a physician's activity and then if there is that high a degree of concern about misbehavior that the patient should be taken off opiates and just be considered too high risk. So we're going to miss out on a few but the community will add epidemic, the pandemic of opiate poisonings will definitely decline, unequivocally and we're already seeing it after just a couple of months of hearsay that this is going to happen because the sea of drugs is going to…the tide will go out on that…on the very high waters that we're seeing right now.

Chuck Agte: Another piece that…in response in just as far as what we've seen in the data and in regard to possible diversion, Siri reminded me of something that I did not mention. Again, this is Chuck Agte. Of the clients that we enrolled in the program after enrolling them in the program and hitting their first rejection for prior authorization we have 10 of those clients who after hitting the first prior authorization stop we received no request for authorization from the pharmacy and the client has never gotten another prescription through Medicaid. So we have 10 people who after being targeted with the program never tried to run another prescription through Medicaid.

Jason Iltz: And Chuck that was 10 of the 100 that were targeted?

Chuck Agte: That's correct.

Jason Iltz: I just wanted to comment, Dr. Tauben. I'm appreciative of the comments that you made regarding sort of where do we go from here? How do we ramp this effort up? Because not to sound unappreciative of all the work this group has done, you've mentioned it's very laborious and from that standpoint we're going to continue to be behind the snowball that's getting bigger and bigger if we can't figure out how to act a little quicker. And I agree, it's a public health emergency right now and I see it on the front lines where, you know, some of the behaviors, some of the requests, it's out of control and I think this group has at least provided an outlet for some of those physicians who have felt like they've been in the corner so

long and had nowhere to move. And working with them will really help. But, you know, we've got a lot of people that are above that 120 and a lot of people that need some help and that are heading, you know, towards these other levels where we've targeted. And so how can we get to them a little bit quicker? So I'm really appreciative of those comments. Right now it sounds like this program is really based on willful participation. And so at what point does the state start to flex their muscle a little bit and say, "Look, this is really a crisis and we have to fix it and there's got to be some mandatory type participation on some level to where we can fix it a little bit quicker." What are your thoughts on that?

Siri Childs: Well what we've built into this program is as soon as Dr. Tauben tells us, or his colleagues tell us at the UW that this dose of opioids or any opioids at all in this patient is inappropriate, then we will follow through and we won't pay for them. You know, we'll let them taper off of them, but we will not pay for them. So, you know, we do plan on saying no.

And then I just wanted to also say that we're going to continue to do these little statistics where we watch the sentinel effect because I can tell you in our other prior authorization programs that when we put a PA on a drug it's amazing what the sentinel effect is. You know, the prescribers don't want the hassle and if they can get help through our program, you know, they'll call on us hopefully and we will help them.

So I wanted to let Janie have an opportunity to talk from her perspective on the agency medical director guidelines because if you don't know Janie has done a lot of work bringing all of that together too.

Janie: Thanks Siri. Certainly Labor and Industry is the lead agency in this effort in terms of developing the AMDG opioid dosing guideline and then our…we're in the current process of revising, which like Dr. Tauben said we're hopeful that we can update the guideline April of this year. So those are some of the efforts in terms of providing more tools to help the provider in managing their patients who they've put on opioid for chronic, non-cancer pain. I think Dr. Tauben just told you that we're going to have tools on urine TOX screen, how to order, what to order and what to do with the results. And so we're hopeful that that provides some guidance to the provider. We will also have tools on different screening tools that's available for abused or identifying risks so that they could better manage

their patient. We also are providing tools on education in terms of patient education, as well as prescriber education.

In terms of answering Jason's question certainly there is a limitation of what the agencies can do. I mean you have to remember that we're a purchaser and we're not entities that are sort of enforcement and regulation. So in that sense our effort has been mainly directed to purchasing and that sort of sense.

There is legislation going on right now that is sort of directing the boards and commission to revise its guidelines and rule to address when consultations should happen and also to address some dosing. I know that Dr. Tauben is going to testify at the Senate Hearing tomorrow on that issue. So there is work being done although, you know, it's not primary…our primary purpose here because we're purchasing…agency.

Vyn Reese: I have a question that's come up in one of my patients recently. What if you suspect somebody of diversion and you say that's terminating your opiate contract or you have really grounds to do that, but you can't really turn it over to law enforcement. It's like a patient/doctor privileged conversation. So it's a really…they're basically going to go out and do that with another doctor. So there's nothing we can do then if a patient is in that interface between medicine and law.

David Tauben: You're right, 100% right. There's nothing you can do but you as an individual provider may be better armed to be able to confront that and then respond appropriately. There was legislation in the State of Washington that was going to follow schedule two drugs statewide and it didn't pass but ran out of money in the financial crisis that the state is facing. It's still on the books and it's my understanding that there will be a registry for schedule two opiates available as part of the actual prescriber. That never got rolled out. I don't know the details of that but that would be another opportunity to identify those sorts of behaviors. You can search a registry and identify the patient is indeed seeing multiple providers or has had previously identified problems. I think the…let me just stress particularly for those who think this is disciplinary and punitive I'm coming. I've just joined you. I'm coming from a primary care practice in the community for 30 years and I'm the strongest patient advocate you're going to find, probably not in this room, but in most of these regulatory discussions. I have to say the overwhelming spirit and

the consensus of the experts who are sitting with the AMDG guideline has been actually inspiring to see that it is very patient centered, it's about patient health and safety. It is not about identifying bad patients or bad…as I said before bad doctors. It's about communicating the fact that this is really not that hard of a problem to fix with the number of structural tools and the legislation that we're forward to, it's already passed the House unanimously; it's going to the Senate tomorrow. We expect it to sail through because it's the same old common sense things we've said. Within one year we'll require that these agencies provide these tools to their licensees. There's no punitive or disciplinary effects. These guidelines don't say, for instance the one case that I saw, we said bring this woman down to 80 mg of morphine, which is well over 320 MEDs and then we'll reevaluate and see how good her function. So we're being very gentle about how we're approaching this on a patient basis because they are very complicated cases. People have been on treatment for decades. The doctor's are just learning…feel the pain medicine is advancing. So we're going at it with this [inaudible] of glove as possible. Legislation I think also is going to be approaching this very delicate and very patient-centered finish.

Patti Varley: This is Patti Varley. I really want to commend this group. I think the work is unbelievably fabulous on a lot of levels and my only hope is it can be marketed in exactly that way because I think anytime it's seen as regulatory or controlling there's an immediate, which I of course am referring to in my questions to you, from my group, which is this immediate somebody wants to control my practice, which is certainly not the case.

The other thing is in a side I just wanted to add as I listen to the stories they were very good, but one in particular struck me, which is something I think happens to me periodically which is we make assumptions because we ask our patients and they tell us and the woman who thought she was on methotrexate was on methadone and to her the meth is all that mattered. And I'm pretty sure, because I have that happen in my office quite often, is that her assumption when she was asked by the rheumatologist was that, "Yes, I'm on that methotrexate stuff," because to her methadone and methotrexate were the same thing. And I think for me, and I think I'm speaking to the choir, our productivity expectations are increasing every day. So my error control is much less. I have to do things more quickly, I'm required to do more paperwork, which is sort of

not just you guys, but part of the times of the world and with that I would love to have someone else helping me to understand that my patient isn't taking what I thought they were. I had that happen recently where a primary care had prescribed a medicine and the family was English as a second language and I had an interpreter in the room and they showed me the bag and the child was supposed to be getting this med and had six refills. Well, they hadn't even finished the first bottle and now they had a higher dose. We talked to the primary care office, he assumed the foot wasn't getting better because the patient wasn't responding to that lower dose. And in actuality they didn't understand the directions. So I think anytime any of us in this wild world who can have somebody help look at it, to me is a gift. So I hope that people can see it that way as well. So thank you.

Karen Wilson: I'm glad to hear you say that because that's how Lana and I view our role in great part is to kind of…is to help. It's to help providers and prescribers that are so harangued and so busy already. It reminds me of a case…Dr. Tauben reviewed this case actually. The gentleman lives in an assisted-living facility and the primary care doctor is prescribing him it's over 4,010 mg methadone tablets a month. It works out to be 12, 10 mg methadone q.i.d. And the gentleman manages his owns meds and the doctor is on level terrified to have the assisted living facility take over his medications for fear that some nurse is going to walk him and give him 12 methadone tabs and kill him. You know? That's how high his fear of diversion is in this case. And yet there's a way to do that that isn't certainly going to, you know, there's a way to do that for the nurse and the doctor and the patient to work together. But it's…working all that out with the assisted living facility takes time. The doctor didn't know that he had to write an order for that to happen and, you know, it was a communication error or whatever. But that's the kind of thing that we try to do and help with when we can.

Vyn Reese: This is Dr. Reese and I also want to commend your work. I think it's incredibly good. I again would say to stress the patient's safety all the way. I mean to the medical…to the doctors. If you stress the patient's safety…Don't talk about costs of the costs or a side benefit, just talk about patient safety and good medicine and sound practice. That's the way to get to the doctors and the doctors will be on board quickly unless they're involved in, you know, some sort of diversion themselves. As long as they're honest doctors they'll…I think that's the way to approach doctors

and I think that's a really valuable thing. Coming in and bringing them in for a tutorial and a sessioning clinic at the Pain Clinic for people who don't know much about it, you know, I think that's an excellent idea. So more education and really solid diligent case finding is the way to go and that's what you're doing.

Lana Griffin: I think that's how we really get their attention is we talk about the patient safety. That's one of the first things we talk about when we discuss, you know, the doctor's know how many milligrams they're prescribing per day, but when I actually direct them to the site, have them go onto the AMDG site with me, have me go onto the morphine equivalent equianalgesic dosage calculator with me and when we type in the actual milligrams that person's taking a day of methadone, OxyContin or whatever, and they see what the MED is they're really often surprised and saying, "I didn't know it was that high." They know the milligram but they don't know the MED and when we talk about, you know…it's a rare occasion when it should be more than 120 and your patient is at 3,000, I think that makes them think a little bit.

Patti Varley: I also think it's not just patient safety, guys, it's public safety because my patients aren't being prescribed it, but they're certainly getting it and we know that people are dying out there because they're taking unprescribed narcotics from other people and mixing it with things that they have no idea. They think if it's prescribed it's safe and that is…I think it's a public safety, not just a patient safety.

David Tauben: Be careful. I'm going to invite you to our next committee meeting for the team.

Vyn Reese: Is there any other discussion?

Siri Childs: I know you probably have heard enough but I do want to ask Scott Best to talk just a very brief moment about the opioid calculator that he has developed in association with this program.

Scott Best: As a collaboraty of effort with Dr. Tauben and the University of Washington doctors we came up with a opioid tapering calculator where you can just put in your short-acting medications, opioids, and your long-acting opioids and it develops…it fills in a schedule that will tell you exactly how much to decrease by every three days or every week

depending on what the starting dose is and then once you get them off of the short-acting it immediately jumps to the long-acting and explains to you how many milligrams to decrease by every week to get them down off of the long-acting opioids and it's fairly easy to use. It works in Excel and so it's something that most providers could use to print off a quick and easy calculation of where they should be with their clients at all times.

Vyn Reese: Where's the website? What's your website that that's on? How do you access that?

Scott Best: The taper plan is on our toolkit website. I'm not sure what the…but if you type in DSHS toolkit in a Google browser I think it comes to the top.

Siri Childs: I can tell you exactly where it is on our pharmacy website and that site is hrsa.dshs.wa.gov/pharmacy and I do believe that there is kind of a sun blast that says "new" and then the taper plan. It's one of the latest things we put on there.

Vyn Reese: Great. Thank you.

Siri Childs: And if any of you have a problem, you know, give me a call and I'll help you with it.

Patti Varley: Siri, are there links from doh.wa.gov? Because that's where a lot of people go for PDL and P&T. I mean to me a lot of these other sites should have connections. Not everybody in the world is going to remember each of these websites but if there's a central place that they tend to go to regarding state rules, regulations, PDL, etc. and then there's a link telling them where to go I would just recommend that because I find all the time that that's the question is, "How do I find it?" And if it's too complicated I think we're losing some of our intent.

Siri Childs: You know, I'm going to ask Dr. Tauben to comment on that because that was one of the issues that was raised at one of the last agency medical director's meetings on what should be out there for the folks to use for these tools and I need direction from you Dr. Tauben.

David Tauben: Could you repeat the question? I was involved in another conversation.

Siri Childs: Sorry. What I'm asking you is the group was deliberating on what tools they would put on the website and I'm wondering what they decided about using Scott's tool for a taper plan?

David Tauben: That tool was not proposed because that's a specific taper schedule. Although it's not a bad idea now that's it brought up as an additional possible device.

Patti Varley: I just think the more complex it is of people to find different pieces really deletes from our intent, which is people utilizing and having easy access to information.

Scott Best: This is Scott Best and I know that on the DOH website they have this new program called Take As Directed and if you go to the Take As Directed website there are links that take you to the toolkit, they take you to AMDG guidelines, they take you to lots of places where you can link to the calculators.

Woman: I just did a Google on DSHS toolkit and it brought up the actual toolkit and it has the links to the tapering guidelines and the narcotics dosage guidelines as well. So it kind of seems to be all on one page here. ‘

Siri Childs: I just want to mention that there is a difference between the opioid calculator that calculates milligrams to morphine equivalent dose and Scott's latest, greatest event that is the taper plan.

Patti Varley: They should both be accessible in the same place.

Vyn Reese: Is there any further questions or discussion? Okay. Then we're adjourned.

Siri Childs: This is Siri and you all do have your assignments for the annual DUR report and they should look very familiar to you except for our brand new members and I've talked to Christine that I'd be happy to let her know the secret to hers. The rest of you should find all of the information that you need in the emails that probably are plugging up your Outlook that will be coming to you if not already from Jeff Graham because I've put together all the meeting minutes and all the PowerPoint's for all the meetings and so you will have everything you need to do your assignments. The first date is due in April and you'll be sending that to HRSA. Okay.

Vyn Reese: Okay. Now we're adjourned.